Exhibit 2

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

- - -

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION	:	MDL NO. 2875 CIVIL ACTION NO. 19-2875 (RBK/JS)
THIS DOCUMENT APPLIES TO ALL CASES	:	HONORABLE ROBERT B. KUGLER

- - -

FEBRUARY 8, 2023

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Remote Videotape Deposition, taken via Zoom, of ALI AFNAN, Ph.D., commencing at 9:23 a.m., on the above date, before Amanda Maslynsky-Miller, Realtime Reporter and Certified Court Reporter in and for the State of New Jersey.

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I N D E X

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Testimony of: ALI AFNAN, Ph.D.

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DEPOSITION SUPPORT INDEX

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Direction to Witness Not to Answer
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Request for Production of Documents
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None

Stipulations
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11 1

Question Marked
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None

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(It is hereby stipulated and agreed by and among counsel that sealing, filing and certification are waived; and that all objections, except as to the form of the question, will be reserved until the time of trial.)

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VIDEO TECHNICIAN: Good morning. We are now on the record. My name is Phillip Todd, I'm a videographer for Golkow Litigation Services. Today's date is February 8th, 2023, and the time is 9:32 a.m.

This remote video deposition is being held in the matter of Valsartan, Losartan and Irbesartan Products Liability Litigation in the United States District Court, District of New Jersey. The deponent is Dr. Ali Afnan.

All parties to this

deposition are appearing remotely and have agreed to the witness being sworn in remotely.

Due to the nature of remote reporting, please pause briefly before speaking to ensure all parties are heard completely.

Counsel's appearances will be noted on stenographic record. The court reporter, Amanda Miller, will now swear in the witness.

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ALI AFNAN, Ph.D., after having been duly sworn, was examined and testified as follows:

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EXAMINATION

- - -

BY MR. SLATER:

Q. Good morning, Dr. Afnan.

A. Good morning.

Q. I'm Adam Slater, I'm going to take your deposition. How are you?

A. I'm good. Thank you very

much.

Q. Great. Have you been deposed before?

A. No.

Q. You understand you must tell the truth in response to every question you're asked today?

A. Yes.

Q. If you're asked a question and you don't understand, for any reason, and you don't feel you can answer it truthfully or correctly, please tell the questioner and we'll refine the question so that you can understand it and that way you can then answer it, okay?

A. Will do.

Q. If counsel objects, let the counsel say whatever they need to say, and then you'll most likely be told to go ahead and answer.

But wait until the objection is stated, okay?

A. Thank you.

Q. When did you first become

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aware that valsartan manufactured by ZHP contained NDMA and NDEA?
A. I think the very first time I became aware of it when -- is when I was approached to act as an expert witness.
Q. What was that date?
A. Sometime early October. I don't have the exact date.
Q. Before that date, you were not aware of the fact that the valsartan manufactured by ZHP contained NDMA and NDEA?
A. I -- no.
Q. Were you aware of the recall of valsartan before that time that you were first approached for this case?
A. No.
Q. Had you ever heard of NDMA before you were approached regarding this case?
A. I had heard of nitrosamines, yes.
Q. In what context?

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A. Discussions with ex-colleagues about presence of NDMA in certain products, but not specific to which product.
Q. When was that? Are you talking about before you were retained in this case?
A. It's before I was retained in this case, yes.
Q. And what was the context where you spoke to colleagues about NDMA?
A. It was just that, you know, NDMA was present in certain products. Again, not specifically mentioned, except that it was in Metformin, because both of us were taking Metformin at that time.
Q. And who was this colleague that you spoke to about this?
A. It's -- it was actually at lunch with a group of ex-colleagues who are pharma executives or pharma employees and FDA employees.
Q. So you were at a lunch where people from the FDA and people from

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pharma were having lunch together?
A. No. As I said, it's ex-colleagues. It's a group of us who have retired, who have left FDA. We were meeting -- we meet every now and then.
Q. You said they were ex -- I'll rephrase.
You said they were pharmacy executives. Did they also work at the FDA, those same people?
A. No, no, no. They were not executives, they were employees of pharma, who have retired from pharma, and also ex-FDA employees; people that I used to work with.
Q. So that was just an informal conversation at a lunch?
A. That was purely an informal, by the way, have you heard of, yes.
Q. When did that occur?
A. Maybe summer of last year.
Q. Summer of 2022?
A. No, I don't remember the exact date. I'm just saying maybe summer

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of 2022.
Q. You said summer of last year, that's why I asked --
A. Yes.
Q. -- if it was 2022.
A. Yes.
Q. If I understand correctly, in your work that you had done before you were approached for this case, you never specifically addressed nitrosamines, NDMA or NDEA; is that correct?
A. Correct.
MR. SLATER: Let's mark as Exhibit-1 the response to the deposition notice.
- - -
(Whereupon, Exhibit Afnan-1, No Bates, Defendants' Responses and Objections to Plaintiffs' Notice to Take Videotaped Deposition (ECF NO. 2258), was marked for identification.)
- - -
MR. SLATER: We can put that

on the screen.
MS. DAVIDSON: So I just want to make sure I understand. Are we going to be having that for everyone to see on the screen?
MR. SLATER: That's why I said put it on the screen.
MS. DAVIDSON: Just the other day you had a different approach you wanted to take, so I wanted to make sure I understood.
BY MR. SLATER:
Q. Doctor, do you see the exhibit -- the document we put up as Exhibit-1 on the screen?
A. Yes.
Q. Have you seen this document before?
A. If you scroll down, I will be able to tell you yes or no. I see only the top of the page.
Thank you.
Q. You can see now the first page. It's titled, Defendants' Responses

and Objections to Plaintiffs' Notice to Take Videotape Deposition.
A. Yes.
Q. Have you seen this document before?
A. Yes.
Q. Did you see the deposition notice?
A. I think so, yes.
MS. DAVIDSON: I think Ali, not being a lawyer, might not know what a deposition notice is. So if you want to ask if he's seen it, I suggest you show it to him.
MR. SLATER: That's all right. He just said he saw it.
THE WITNESS: No, I -- this is what I have seen.
BY MR. SLATER:
Q. Great. The questions are all on this, too. So we're good.
Okay. Did you go through each of the requests and attempt to provide the documents that were requested

in the deposition notice to the lawyers who hired you?
A. Yes.
MS. DAVIDSON: Dr. Afnan, I wanted to object to that question, and you did not give me time. So please make sure when Adam asks you a question, I know Adam talks very fast, and that encourages everyone around him to talk very fast, but it doesn't give -- I am not fast. It doesn't give me time to object.
So I do object to that question.
And please make sure that you allow me time in this deposition to object.
THE WITNESS: Sure. Sorry. Will do.
MR. SLATER: Chris, let's go to the end, to Number 17, please. Maybe we can make it a little bigger. Perfect.

BY MR. SLATER:
Q. Looking at Number 17, it requested, Any cGMP guidance, rule, protocol or procedure, drafted in whole or in part by Dr. Afnan, related to the development or manufacture of API or finished dose and/or with regard to genotoxic or other impurities in API or finished dose.
Do you see that?
A. Yes, I see that.
Q. In response, we were told that you were involved in the development of FDA's process analytical technology guidance in -- dated 2003, process validation guidance 2011, and guidance for industry, Q8 pharmaceutical development, 2006, correct?
MS. DAVIDSON: Adam, I don't see that. Is that --
MR. SLATER: It's in the response in the first paragraph of the response that you guys wrote.
MS. DAVIDSON: Oh, I see

where you are. If you can point to where you're reading on the page, it would be helpful.
BY MR. SLATER:
Q. Do you see where I just read, Doctor?
A. What you -- yes, I do.
Q. Did you ever draft, in whole or in part, any other guidances, rules, protocols or procedures related to the development or manufacture of API or finished dose and/or with regard to genotoxic or other impurities in API or finished dose?
MS. DAVIDSON: Adam, if you could possibly talk a little slower. I can't --
MR. SLATER: I'm sorry, I'm -- I'm doing the best I can.
BY MR. SLATER:
Q. Are there any others, Doctor?
A. No.
Q. Do you agree that cGMP is an

obligation -- rephrase.
Do you agree that compliance with cGMP is an obligation of a pharmaceutical manufacturer like ZHP?
MS. DAVIDSON: Objection.
BY MR. SLATER:
Q. Yes or no?
MS. DAVIDSON: I'm going to object to that question. If that was a second question, I'm objecting again. I think it's vague.
BY MR. SLATER:
Q. Can you answer the question, please, Doctor?
A. So --
MS. DAVIDSON: Adam, give him a minute. Come on.
THE WITNESS: So cGMPs are a minimal requirement for operation which industry pharma companies are expected to be aware of and to apply to their processes and their practices.

BY MR. SLATER:
Q. Do you agree with me that ZHP was required to comply with cGMP at all times -- at all times in the development and manufacture of valsartan?
MS. DAVIDSON: I'm going to object again. And, also, I believe it was asked and answered.
THE WITNESS: I did actually answer it.
BY MR. SLATER:
Q. Yes or no, please.
MS. DAVIDSON: Adam, you know very well that he's not required to give you yes or no. He's allowed to answer the question as he deems fit and to provide whatever context he thinks is necessary.
If I understand this question, I believe we've been down this road in this MDL proceeding.
BY MR. SLATER:

Q. Please answer the question, Doctor.
A. GMPs specify what needs to be done and not how the things are to be done in a pharma company; and ZHP adhered to the GMPs.
Q. Now I'm going to ask the question again.
I didn't ask you any of that other things that you're talking about. So our deposition will go much more smoothly if I ask you a direct question to just answer it directly and not talk about other things. So I would appreciate it if you could try to do that, please.
Was ZHP required to comply with cGMPs at all times during the development and manufacture of the valsartan that they manufactured and sold?
MS. DAVIDSON: I'm going to object again. At this point I think you're badgering the

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witness.
THE WITNESS: So I have answered the question. And I can't not give a dimension to my response.
However, if you say, were they required -- was ZHP required to apply it, the GMPs, my -- I have to make a lot of assessments to say -- to answer that question.
Again, I'll repeat, GMPs are a list of what-to-dos, not how-to-dos, and ZHP adhered to the GMPs.
BY MR. SLATER:
Q. I didn't ask you if they adhered. I didn't ask you if it's a how-to. I didn't ask you any of those questions.
So I thought this would be the easiest question of the deposition. So I'm going to try it again.
Do you agree with me that ZHP was required to comply with cGMPs in

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the development and manufacture of the valsartan API that it manufactured?
MS. DAVIDSON: Objection again. Asked and answered. Vague. And at this point, badgering the witness.
BY MR. SLATER:
Q. It's a yes-or-no question, Doctor.
MS. DAVIDSON: Again, I believe I stated this two minutes ago, but I'll state it again. He is not required to answer yes or no if he does not feel that yes or no is an adequate answer to the question. There's no thought control here.
I'm sorry, Dr. Afnan.
THE WITNESS: A yes or no does not actually address the question. I think the question is vague.
BY MR. SLATER:
Q. You think it's a vague

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question to ask if ZHP was required to comply with cGMPs in the development and manufacture of valsartan; is that your testimony?
MS. DAVIDSON: I'm sorry. Objection.
BY MR. SLATER:
Q. Please answer.
A. So the --
MS. DAVIDSON: Hold on. You're mischaracterizing this testimony. And, also, every time I object you then ask a second question so that I have to object again.
So I suggest that after I object, Dr. Afnan knows that he's supposed to answer a question, unless I instruct him not to answer. So I don't think it's helpful to badger him after I object, pressuring him to answer the question. He knows there's a question pending.

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And then it's unclear to me, when you badger him again, whether I need to object again for the record.
Do you want the court reporter to read back the question, Dr. Afnan, since we distracted you with our back-and-forth?
THE WITNESS: Yes, please.
- - -
(Whereupon, the court reporter read the following part of the record:
"Question: You think it's a vague question to ask" --)
- - -
MR. SLATER: I'm just going to state for the record that I think that defense counsel is obstructing the deposition.
I'm going to now continue.
BY MR. SLATER:
Q. Dr. Afnan, are you saying

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that my question is vague when I ask you if ZHP was required to comply with cGMPs in the development and manufacture of valsartan?

MS. DAVIDSON: Wait a minute. Adam, are you taking back the last question that I'm having the court reporter read back?

MR. SLATER: I'm not going -- I'm not going to go back-and-forth with you. You're eating up my time already. I'm not doing this with you.

So I'm going to continue my deposition.

MS. DAVIDSON: So I assume that question was stricken.

BY MR. SLATER:

Q. Please answer.

A. The reason I believe your answer is vague is -- your question is vague is because this is not a simple yes or no. It depends what the definition of cGMPs are, because, as I said, cGMPs are

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a list of what-to-dos as stipulated by the Food and Drug Administration.

How those are effectively put into practice is done through the procedures of the firm.

Q. And when the firm, then, puts those principles into effect, those standard operating procedures and internal procedures become requirements under cGMP, correct?

MS. DAVIDSON: Objection.

THE WITNESS: That's a circular argument. They don't become requirements under cGMP, they become, effectively, the practicing standards of the firm. And the firm can change those as well. There is a procedure for changing those. They are not, you know, written once and for all.

BY MR. SLATER:

Q. How do you define cGMP?

A. It is the cGMPs are defined, for API drug manufacturers in Q7 -- ICH

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guidance Q7. For drug product manufacturers, it's defined in 210 and 211 of the code of federal regulations.

Again, those are the what-to-dos and not the how-to-dos.

Q. The how-to-do is pursuant to internal standard operating procedures that are put into place by the firm; is that what you're telling me?

A. Yes.

Q. Are you saying that ZHP was only required to comply with its own internal standard operating procedures with regard to cGMP and was not required to comply with ICH or other outside sources of cGMP guidance?

MS. DAVIDSON: Objection. Mischaracterizes the witness's testimony.

THE WITNESS: That's not what I said.

BY MR. SLATER:

Q. At all times that -- rephrase.

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At all times that ZHP developed and manufactured valsartan, ZHP was required to comply with both the outside standards for cGMP that applied to its manufacture and development of valsartan, as well as the internal protocols that had been implemented by ZHP, pursuant to those outside sources; would you agree with that statement?

A. Can you --

MS. DAVIDSON: Objection.

THE WITNESS: Can you tell me which outside standards, please?

BY MR. SLATER:

Q. For example, ICH Q7.

A. If you look at ICH Q7, on the first page of the text of the document, as well as every other guidance, FDA makes a statement that this guidance is not binding and that it is a recommendation and it's the current thinking of FDA regarding a topic.

Q. Please define for me which

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cGMP standards applied to ZHP in the development and manufacture of valsartan. Please list for me those sources of objective authority, whether internal or external to ZHP, which applied to them and to which they had to comply.

MS. DAVIDSON: That was two questions.

MR. SLATER: Great.

BY MR. SLATER:

Q. Please answer.

MS. DAVIDSON: Which one, the first or second?

MR. SLATER: I'm not going to -- I'm not going to banter with you.

BY MR. SLATER:

Q. Please answer the question.

MS. DAVIDSON: I'm going to object. That was a compound question.

I think that the rules of a deposition are you ask one question at a time, and there were

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two in there.

BY MR. SLATER:

Q. Please answer the question.

A. Can you ask the question again, please?

Q. Please list for me each source of -- rephrase.

Please list for me each standard that applied to ZHP's development and manufacture of valsartan with regard to cGMP.

I want to know what -- the universe of what you believe applied to them that they had to adhere to is.

MS. DAVIDSON: I'm going to object again. I think it actually, Adam, I think it's important for this deposition to understand, when you say ZHP, do you also mean its subs or are you specifically referring to ZHP?

MR. SLATER: I don't even understand your question. I'm not going to go back-and-forth.

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BY MR. SLATER:

Q. Please answer the question.

A. I have here in front of me ICH Q7. Q7 is a guidance issued by FDA -- ICH and adopted by FDA. It's title is, Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients, Guidance for Industry, September 2016.

On the very Page Number 1, which is after Page Number 4, 4 as in IV, it states, Good manufacturing practice guidance for active pharmaceutical ingredients. Guidance for industry.

And there is a black box which says, This guidance represents the current thinking of the Food and Drug Administration on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

So --

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Q. Is that your complete answer to my question?

A. You're asking me for -- again, you know, this goes back to the very first question, one of the previous questions, of you saying specify the standards.

My point is, the GMPs are a set of what-to-dos and not how-to-dos. Industry needs to follow the how-to-dos and those how-to-dos are based on -- for API manufacturers, are based on Q7, which ZHP followed and did.

Q. I'd like you to list for me -- rephrase.

Please list for me those cGMP standards, whether they are external to ZHP or internal to ZHP, such as standard operating procedures that applied to ZHP in its development and manufacture of valsartan.

I need to know the list of what you believe they were required to comply with when they developed and

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manufactured the valsartan.
Please answer the question.
MS. DAVIDSON: Objection. Compound. Asked and answered. Vague.
BY MR. SLATER:
Q. I'm not asking you to read the standards to me. I'm asking for you to list them for me, please.
A. So -- so if I'm going to list them, Mr. Slater, I would go to ICH Q7, okay; and I would go to the table of contents.
Would you like me to list them for you?
Q. I don't need you to list for me the table of contents.
If you think that ICH Q7 was something that ZHP needed to comply with, per my question, you can say ICH Q7.
I don't need you to read me the table of contents.
A. The sections -- sorry.
MS. DAVIDSON: Dr. Afnan,

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you've got to leave me time to object.
Because I object to that. I don't even think it was a question.
THE WITNESS: The current standard in industry, and as practiced by the regulators, is to have a quality system which is effectively defined through a guidance of FDA, which talks about quality systems.
And it's defined -- or it's stipulated as what it needs to have in Q7. It requires, effectively, the Quality 7, the training of the personnel, the buildings and facilities, the process equipment, documentation and records, material management, production and in-process controls, packaging and identification labeling for APIs and intermediates, validating the

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lab controls, validation, change control, rejection of materials, complaints and recalls.
Now, about the internal standards, that would be the list of ZHP's SOPs, which I do not have. That was beyond the scope of my agreement.
BY MR. SLATER:
Q. When you say "beyond the scope" of your agreement, what do you mean?
A. Not agreement, my agreement. It was -- I was not tasked with assessing all the GMPs of ZHP.
Q. Got it.
MR. SLATER: We can take down the deposition notice. Let's put up as Exhibit --
BY MR. SLATER:
Q. Well, let me ask you, Doctor, do you have your report in front of you?
A. I do.

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MR. SLATER: We have a December 23, 2022, report. For the record, we'll put it up on the screen just so everybody can seen it. And it will be for the court reporter to have it. But that will be Exhibit-2.
- - -
(Whereupon, Exhibit Afnan-2, No Bates, 12/23/22 Expert Report of Ali Afnan, Ph.D., was marked for identification.)
- - -
BY MR. SLATER:
Q. Doctor, subject to an e-mail that we got that had some corrections of a few things within the report, is this the only report -- well, rephrase. Let me ask it differently.
Is this the only report you've written in this case?
A. I -- the amended report was, I think, submitted on January 11, 2023.
Q. Sorry. I had a malfunction

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here.
Let me ask the question again.
The December 23, 2022, report we have on the screen is the first report you wrote in this case, correct?
A. Yes.
Q. Did that contain all the opinions you had formed at the time that you authored that report?
MS. DAVIDSON: Objection.
THE WITNESS: Did it contain -- can you -- can you rephrase the question, please?
BY MR. SLATER:
Q. On the screen we have your December 23, 2022, report.
A. Yes.
Q. Did that report contain the opinions you had formed at the time that you signed that report on December 23, 2022?
A. Yes.
MR. SLATER: Let's take that

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down and put up as Exhibit-3 the amended report now.
- - -
(Whereupon, Exhibit Afnan-3, No Bates, 1/11/23 Expert Report of Ali Afnan, Ph.D., was marked for identification.)
- - -
BY MR. SLATER:
Q. Exhibit-3 is the January 11, 2023, report.
Is that the second report you wrote in this case?
A. Yes.
Q. Can you tell me what, if anything, is different between the January 11 report and the December 23, 2022, report?
I don't need you to find page numbers. If you can just tell me generally what you did with the report between those two dates.
MS. DAVIDSON: Objection.
BY MR. SLATER:

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Q. Let me ask the question differently.
Why did you serve an amended report on January 11, 2023?
A. I discovered typographical errors in it. And then also I came across a version of M7 which I had not referred to in my December 23 report, it was the earlier version of M7.
Q. In your work outside of this case, did you ever apply M7 in any case, any situation?
A. In my work I have -- during the development phase of working with some clients, I do look -- I have looked at M7.
Q. What was the context?
MS. DAVIDSON: Adam, before you go on.
Dr. Afnan, as Adam has cautioned his witnesses, I know that some of your consulting work may be confidential. And you're not obligated to violate

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confidentiality of relationships or agreements with clients in order to respond to this deposition.
So please keep that in mind when you're asked any questions about your consulting work.
Thank you.
THE WITNESS: Thank you.
As I said, it was during drug development processes.
BY MR. SLATER:
Q. Was that API drug development process or finished dose drug development process?
A. In both cases, it was a new drug, so it was both development of the API and also, then, development of the drug product.
Q. When did that occur?
A. Over the last five years. I don't have the exact dates.
Q. Let's go back to Exhibit-2.
Attached to Exhibit-2 is

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your C.V., curriculum vitae, correct?
A. Yes.
Q. You're currently the president and founder of Step Change Pharma, Inc.
What is that company?
A. It's a consulting company.
Q. What do you consult on?
A. Various projects all related to pharma; from drug development, which is a much lesser extent of my work, to GMP remediation, manufacturing enhancements.
Q. When you say drug development is a lesser part of your work, what do you mean by that?
A. I have -- I have, maybe, two or three clients who work in that area.
Q. What does GMP remediation mean?
A. Firms who have gotten into trouble with FDA or the European Agency or any of the others and need to effectively remediate.

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Q. Did ZHP need to do GMP remediation?
A. They got 483 obligations, which they addressed. That's what I call remediation.
Q. Have any of your clients received FDA warning letters for which you had to perform GMP remediation?
MS. DAVIDSON: Objection.
BY MR. SLATER:
Q. You can answer, Doctor.
A. Yes.
Q. How many times?
A. I don't recall. Truthfully, I don't recall.
Q. Is it a good thing for a pharmaceutical manufacturer to receive a warning letter from the FDA? Does the manufacturer like getting warning letters? Is that something they like to get?
MS. DAVIDSON: Objection. That was three questions. Vague. I think that's all.

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MR. SLATER: I'll ask it again.
BY MR. SLATER:
Q. Do pharmaceutical manufacturers hope to receive warning letters from the FDA?
MS. DAVIDSON: Objection.
THE WITNESS: Pharma manufacturers are in the business of making a drug or drugs and selling them, not receiving warning letters.
BY MR. SLATER:
Q. That's -- I didn't ask you what business they're in. I asked you a simple question.
Is the answer yes or no?
MS. DAVIDSON: Objection. Maybe rephrase the question.
MR. SLATER: I don't think I need to.
BY MR. SLATER:
Q. Can you answer, please?
MS. DAVIDSON: Well, I'm

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objecting again.
THE WITNESS: The answer is no, because that's why they engage third parties to do the work to help them.
BY MR. SLATER:
Q. What do you mean by that, that's why they retain third parties to do the work to help them?
I don't understand. What's that mean?
A. They -- at times, firms work with external parties like me, a GMP remediation company, to assist them with putting -- you know, correcting whatever has been identified, partly -- yeah.
Q. ZHP received a warning letter in November 2018, correct?
A. Yes.
Q. That letter -- rephrase.
That warning letter identified violations of cGMPs, correct?
MS. DAVIDSON: Objection.
BY MR. SLATER:

Q. Can you answer the question, please?

MS. DAVIDSON: I believe the witness was thinking. And I do want to state for the record --

MR. SLATER: I think the problem is, Jessica, when you're objecting, he doesn't know if he's allowed to answer the question.

MS. DAVIDSON: No, I explained at the beginning of the deposition --

MR. SLATER: I don't want to argue with you. I'm not going to engage with you.

MS. DAVIDSON: Okay. I don't want to engage with you either, Adam.

But I want to point out that you had many witnesses last week who took up to five minutes to answering questions. We did not badger them or interrupt the deposition to address that. Many

of your witnesses took significant periods of time.

If Dr. Afnan is thinking, I don't think badgering him to answer more quickly is fair or appropriate deposition practice.

MR. SLATER: I disagree with everything you just said and I'm going to wait for the answer.

THE WITNESS: So a statement on the warning letter is actually boilerplate language which is on every warning letter which FDA issues.

BY MR. SLATER:

Q. The warning letter states, in part, This warning letter summarizes significant deviations from current good manufacturing practice, cGMP, for active pharmaceutical ingredients, API.

The letter says that, right?

MS. DAVIDSON: Objection. If you're asking him to confirm the reading of a document,

obviously that document needs to be in front of him. I don't think Dr. Afnan memorized the warning letter or maybe he did.

MR. SLATER: Do you want to testify for him that he didn't memorize the warning letter or do you want to try to let him to answer the question?

MS. DAVIDSON: I don't know, maybe he did memorize it. My point is, if you're asking --

MR. SLATER: Why are you trying to block him from answering the question?

MS. DAVIDSON: I am not trying to block him from answering the question, Adam. As somebody who repeatedly told his witness last week to look at a document, I think this is kind of an ironic accusation.

If you want Dr. Afnan to testify as to whether you read a

document accurately, obviously he needs the document in front of him.

BY MR. SLATER:

Q. Doctor, can you answer the question, please?

A. I would appreciate, actually, if you could put it up.

Q. Okay. You said that the letter contained boilerplate language that's found in all warning letters.

Do you remember you said that a few moments ago?

A. Yes.

Q. What's the boilerplate language you were referring to?

A. If you put it up, I'll show you.

Q. Let's put it up.

MR. SLATER: This will be exhibit, what, 3? 4, okay. Exhibit-4 will be the warning letter.

- - -

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(Whereupon, Exhibit Afnan-4, PRINSTON00077339-7344, 11/29/18 Letter, Godwin to Du, was marked for identification.)

- - -

THE WITNESS: If you would be kind enough to scroll down, please.

So the boilerplate language is, This warning letter summarizes significant deviations from current good manufacturing practice, cGMP 4.

And then the rest of it would be for whether it's testing, whether it's APIs, or whether it's for drug product.

The next paragraph is also boilerplate language.

BY MR. SLATER:

Q. Does every manufacturer of pharmaceutical products receive a warning letter that contains the boilerplate language you just described every year?

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A. So if you can read the question back to me, because that was an interesting question.

Q. Well, I'll ask it -- I'll ask it differently. Well, actually, I'll ask it again.

Does every pharmaceutical manufacturer, under the jurisdiction of the FDA, receive a warning letter every year with regard to all products that they manufacture that contains the two boilerplate sections you just pointed out to me?

MS. DAVIDSON: Objection.

THE WITNESS: If a firm is inspected, and it's very rare that FDA inspects every year, if a firm is inspected and observations are given to it, the firm responds.

FDA will then make a determination, based on the observations, the response and the EIR whether to issue a warning letter or not.

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Every warning letter that is issued has those two paragraphs in it.

BY MR. SLATER:

Q. The warning letter sent by the FDA to ZHP, dated November 29, 2018, identified what they described in their letter as significant deviations from current good manufacturing practice for active pharmaceutical ingredients.

That's what the letter says, correct?

A. That's what the letter says, yes.

Q. The warning letter also states, Because your methods, facilities or controls for manufacturing, processing, packing or holding do not conform to cGMP, your API are adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug and Cosmetic Act, correct?

That's what it says in the letter, correct?

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A. That's what it says in the letter.

MR. SLATER: You can take the letter down.

BY MR. SLATER:

Q. When you were at the FDA, did you have any responsibility to oversee API manufacturing of drugs?

MS. DAVIDSON: Objection.

THE WITNESS: In my years at FDA, and the way FDA currently works, there is no individual person responsible for API manufacturing. It's effectively managed through either the review division or through ORA for inspection, but primarily through the review division.

And, no, I was not solely individually responsible for API manufacturing.

BY MR. SLATER:

Q. When you were at the FDA, did you have any responsibility in

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connection with any matters focused on API manufacturing of pharmaceutical drugs at any time?
MS. DAVIDSON: Objection.
BY MR. SLATER:
Q. Let me ask the question differently. I just want to make it cleaner.
A. Yes.
Q. At the FDA -- I'm going to ask it differently.
At the FDA, did you have responsibility in any way, or involvement in any way, with any matter involving the manufacture of API?
A. So was I involved with the review of API applications or documentation? The answer is yes.
But your question is vague in saying I was responsible solely for manufacture of API.
Q. I never asked if you were solely responsible. So the vague point that you're concerned about, I never

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actually asked that.
A. My apologies.
Q. You don't have to apologize.
What I'm asking, in a broad sense, is, what, if any, involvement you ever had with any matter involving API manufacture when you were at the FDA?
MS. DAVIDSON: Objection.
THE WITNESS: I believe I've answered that.
BY MR. SLATER:
Q. Just to be clear, would you please tell me what involvement you ever had with any matter involving API manufacturing?
A. I have been involved with the review of API manufacturing processes.
Q. In what context would you have reviewed the processes? Would it have been where you went out and did an inspection? Would it have been review of an application? Would you have reviewed a document? Would you have had a

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conversation with someone?
Can you explain to me what that involvement would have been?
A. The review --
MS. DAVIDSON: Whoa. You got to give me a minute to object.
That was, like, seven questions. So I'm not sure -- it was super compound.
If you know which one to answer, go ahead.
THE WITNESS: Which one was I involved with? The review process and approval process of APIs in FDA is very -- complex is the wrong word.
It's a team effort. So there are multiple divisions, multiple groups, who actually get engaged in the review process.
The review process consists of, for APIs, depending whether it's a generic or whether it's a brand, whether it's existing or

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whether it's new, it will effectively be reviewed by different multidisciplinary groups.
And where I have been involved was to look at the manufacturing processes in relation to APIs.
It is then reviewed. The agency, the FDA, asks for an inspection of the facility, if it doesn't have enough information about the GMP status of the facility. And then it makes a collective decision.
BY MR. SLATER:
Q. I didn't ask you what the FDA does to oversee API. I asked what involvement, if any, you've ever had when you were at the FDA with any matter involving API, what you did.
A. I answered that.
Q. I need you to tell me what you did.

MS. DAVIDSON: Objection.
THE WITNESS: I answered that. I said I was involved with the review of the application to FDA.
BY MR. SLATER:
Q. When you say "review of the application to FDA," what specific application is that? Is there a name for that application?
A. That comes as part of either ANDA, NDA or DMF.
Q. And in your role, what would your responsibility have been in looking at those applications? What were you looking for? What were you doing?
A. My role was to look at, effectively, the manufacturing process, the controls, what FDA calls chemistry manufacturing and controls of the processes.
Q. What were you looking for when you were looking at that material?
A. Whether the process was

feasible or not, whether the critical process parameters which have been identified correlated to the critical quality attributes and how those attributes were controlled, and whether they met USD requirements or if those were in-house specifications.
Q. Do you hold yourself out as an expert in organic chemistry?
A. No, not as an expert in organic chemistry. No.
Q. Are you holding yourself out as an expert in FDA regulation of API and finished drug products?
A. I have extensively worked in the API and drug product domain.
Q. Do you hold yourself out as an expert with regard to the identification of genotoxic impurities in drug substances?
MS. DAVIDSON: Objection.
THE WITNESS: That's actually two questions. And I am not a toxicologist, so I'm not one

to determine genotoxicity of a chemical compound.
BY MR. SLATER:
Q. When you worked at AstraZeneca, were you involved in the development or manufacture of API?
A. Yes.
Q. What was your responsibility in that context?
A. Process control.
Q. What does that mean, process control?
A. Controlling the manufacturing process to end up with the result that was determined as desirable.
Q. When you say to end up with the result that was desired, what does that mean?
A. So that the API had the right yield, the right specifications, environmental conditions were met, process went as planned.
Q. Was it a cGMP requirement that the process control would result in

an output of product as you just described it?
A. Was it a cGMP requirement -- so I was involved in API manufacturing for new products.
What is the GMP requirement? Once it's approved, your controls need to provide consistent quality, consistent -- you know, consistently meet specifications; so the definition here is based on meeting specifications.
Q. Is that required by GMP, the manufacture of a drug product, whether API or finished dose, that meets the specifications?
A. So --
MS. DAVIDSON: Objection. Please, Dr. Afnan, 30 seconds is all I ask.
THE WITNESS: Okay. Sorry. Can you ask the question again, please?
BY MR. SLATER:
Q. Sure.

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You indicated that the process control was intended to ensure the output of drug product with consistent quality, consistently meeting the specifications.

I'm asking if that was required by cGMP?

A. The question requires a very detailed answer; and the very detailed answer you're going to object to.

Okay. You say that is, it a GMP requirement? So, effectively, if you develop a product and you say, for example, its yield is between 80 percent to 85 percent, one of the requirements are that you have a -- develop a trend of meeting that.

Now, once you develop, you know, one batch produced at 90 percent and another batch produced at 70 percent, that's not a deviation from the GMPs. You need to look at it. But that's not a deviation from the GMPs.

That's why I'm struggling

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with the question.

Q. One of the things you said that your process control was supposed to ensure was consistent quality.

Is the output of API with consistent quality a requirement of cGMP?

A. So, again, you know, consistent quality, it depends how -- how the specs are -- specifications for the API are determined.

So if the specifications, which are approved by if regulator, you know, should you meet those specifications with every batch? And the answer is, that's the ideal goal. Will you meet those every single time? And the answer is, no, you will not.

So, again, it's not a black-or-white response that I can give you.

Q. Does cGMP require that a manufacturing process yield API that meets the specifications for that API?

MS. DAVIDSON: Objection.

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THE WITNESS: I think I've answered that. But, again, I'll try.

cGMPs allow you to fail in manufacturing a batch. So it's not a case of, you know, the cGMPs require that if I make 1,000 batches, they all need to be identical.

cGMPs do allow batch failures. If a batch fails, that means it doesn't meet its specifications. cGMPs allow that.

BY MR. SLATER:

Q. Would I be correct that cGMP allows for the possibility of a batch failure, as you just described it, as long as you detect and identify the batch failure?

MS. DAVIDSON: Objection.

THE WITNESS: That's a circular question. If a batch fails and it is rejected, then, obviously, it doesn't reject

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itself. It is assessed, analyzed and, therefore, the quality unit rejects it.

So if the quality unit reject it, then -- that's what I meant by your question is circular.

BY MR. SLATER:

Q. So if I understand correctly, cGMP allows a batch failure, but that's only if the batch failure is identified by the quality unit and then that batch failure is identified and that batch is rejected? Do I understand that correctly?

MS. DAVIDSON: Objection. Mischaracterizes his testimony.

THE WITNESS: Yes, it does mischaracterize my testimony. That's not what I said.

BY MR. SLATER:

Q. All right. So let me ask you a different question, then.

Is it your testimony that

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cGMP does not require that the API manufactured with a drug process -- rephrase.

Are you telling me that cGMP does not require that the API manufacturing process result in the output of API that meets the approved specifications for the drug?

MS. DAVIDSON: Objection. Again, mischaracterizes testimony.

MR. SLATER: I'm asking the question.

MS. DAVIDSON: You said, are you saying, so I thought you were characterizing his prior testimony. If not, great.

THE WITNESS: Your approach to cGMPs is that the cGMPs determine -- define every activity of every day. Again, I go back to very early on when I was saying, you know, the GMPs define what to be done and not how to be done.

So the cGMPs do not specify

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that, you know what, the batch needs to be rejected or approved. The cGMPs create a system, and that's the uniqueness of the U.S. regulations, creates a system within which a manufacturer manufactures, tests and comes to a disposition decision.

So cGMPs is a system within a system. It's like saying, here is a system for operating within pharma, and then I have -- I have a bad batch or I have a semi-bad batch. Again, not every result of -- related to specifications of a batch, you know, can result in a rejection.

BY MR. SLATER:

Q. What is the purpose of having specifications for a manufactured API?

MS. DAVIDSON: Objection. Vague.

THE WITNESS: If -- I am not

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sure I actually understand your question clearly.

BY MR. SLATER:

Q. Do you want me to explain it?

A. Please.

Q. If you don't understand it clearly, then I don't want you to answer a question you don't understand clearly.

A. Thank you.

Q. Do you know what specifications for API means? In general, do you understand what that means?

MS. DAVIDSON: Objection.

THE WITNESS: You have a definition for that, right?

BY MR. SLATER:

Q. I'm asking you, you're the expert. So tell me, what's the definition of what the specifications for API is?

What are specifications? Why do they exist?

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A. They are --

MS. DAVIDSON: Objection. Ali, I don't want to yell at you. You got to give me time to object.

THE WITNESS: You know, specifications are effectively the -- the bandwidth that we operate in, okay. That's what the specification is, it specifies a parameter and says, this parameter, plus or minus a variance, needs to be met or should be met.

There are specifications and there are limits. So limits are -- in the regulated pharmaceutical world are internal to the firm. Specifications is what you agree with the regulator.

BY MR. SLATER:

Q. What is the purpose of establishing specifications for a manufactured API?

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A. What's the purpose of specifications for a manufactured API? It's so that when we talk about that API, we are talking about the same product, regardless of who the manufacturer is.

However, there are differences between those manufactured products by different manufacturers.

MS. DAVIDSON: We've been going about an hour. Is this a good time for a break?

MR. SLATER: I'm actually ready to keep going for as long as we possibly can. I don't need a break.

MS. DAVIDSON: Dr. Afnan, do you need a break?

THE WITNESS: I would appreciate a break.

MS. DAVIDSON: Okay. Let's take ten minutes.

VIDEO TECHNICIAN: We're off the record at 10:37 a.m.

- - -

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(Whereupon, a brief recess was taken.)

- - -

VIDEO TECHNICIAN: We're back on the record at 10:47 a.m.

BY MR. SLATER:

Q. You said the purpose of specifications for an API is so that when we talk about the API it's the same product, regardless of manufacturer, correct?

MS. DAVIDSON: Objection.

THE WITNESS: Okay. "Same" is an interesting word to use. And if I used same, it was -- it has to be qualified.

So, effectively, when we look at USP monographs, it defines specifications for an API. And that has a range for purity, impurity, unknown impurity, so on and so forth.

BY MR. SLATER:

Q. When you say there's "a

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range," what do you mean?

A. So, for example, it will say 98 percent to 102 percent purity. It says, you know, impurities or a specific impurity below a certain limit. It states unknown impurities below .1 percent or 1 percent or .5 percent. It varies from product to product.

Q. If there are unknown impurities -- well, rephrase.

Are all -- rephrase.

Are all unknown impurities evaluated in the same way in terms of whether or not it's acceptable for them to exist in an API?

MS. DAVIDSON: Objection.

THE WITNESS: If it's an unknown impurity, how would one assess it to see if it's supposed to be there or not? So could you please rephrase your question?

BY MR. SLATER:

Q. No. Actually, I think I'll ask a follow-up question.

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Unknown impurities need to be assessed in order to identify what they are because all impurities are not treated the same, in terms of how much can exist in an API or drug product, correct?

MS. DAVIDSON: Objection.

THE WITNESS: ICH Q3A specifically defines and allows for unknown impurities to remain in a product. And an unknown impurity is that, it's not known; we don't know what it does. You -- you know, all that is there is what level and what the limit is for it.

BY MR. SLATER:

Q. If an unknown impurity is below whatever threshold you are applying as a manufacturer and the amount of that impurity under that threshold is sufficient to kill every single person who takes the drug product, is that acceptable?

MS. DAVIDSON: Objection.
THE WITNESS: If it's an unknown impurity, how would a manufacturer know of the effect of an unknown impurity?
BY MR. SLATER:
Q. In forming your opinions in this case, is it your foundational assumption that it's impossible for an API manufacturer to identify the unknown impurities created by a manufacturing process?
MS. DAVIDSON: Objection.
BY MR. SLATER:
Q. Let me ask the question differently.
A. Okay.
Q. Is it your testimony that it is impossible for an API manufacturer, like ZHP, to identify the source of impurities that are below the applicable threshold but are not known?
Are you saying it's impossible to figure out what they

actually are?
MS. DAVIDSON: Objection.
THE WITNESS: I didn't say it's impossible. We need to go back to ICH and see what ICH says, even though it's a guidance and it allows for unknown impurities below a certain limit to be present.
There is no requirement to go and identify every single unknown impurity and see whether -- you know, what the function of that impurity is.
BY MR. SLATER:
Q. So that comes back to my prior question.
If there's no requirement to identify all unknown impurities, would it be acceptable, under cGMP, if there was an unknown impurity below the ICH Q3A threshold that, if ingested by a human being, would kill the person within one day?

A. Wow.
MS. DAVIDSON: I don't know if that "wow" covers my objection. You didn't give me a chance.
But I was intending to object.
THE WITNESS: Well, that was an objection from me.
MS. DAVIDSON: I don't think you're allowed to do that, Dr. Afnan.
THE WITNESS: Sorry.
MS. DAVIDSON: That's my job.
THE WITNESS: Can you repeat your question, please? Or I would really prefer you to rephrase the question.
MR. SLATER: Please read the question back to him, please.
- - -
(Whereupon, the court reporter read the following part of the record:

"Question: So that comes back to my prior question.
"If there's no requirement to identify all unknown impurities, would it be acceptable, under cGMP, if there was an unknown impurity below the ICH Q3A threshold that, if ingested by a human being, would kill the person within one day?")
- - -
MS. DAVIDSON: Objection.
THE WITNESS: I don't even know how to begin to answer that question, because it is such a far-fetched question that -- you know, if it was below the threshold limit?
If it's below the threshold limit, the pharma manufacturer doesn't know about it, because it's unknown.
So the GMPs allow -- or, more specifically, the

specifications allow to have unknown impurities.

Now, if it's a generic API, then it's following the branded API. If it's a brand API, then it will have gone through multiple different clinical studies where the intent would have been to identify a poisonous compound.

BY MR. SLATER:

Q. Are all potential impurities subject to the same threshold?

A. So the threshold depends on your analytical methodology. It's not just the case of, you know, here I draw a line and I call it a threshold and then move on.

So I think your -- your question needs exploring, it needs to be changed.

Q. Did you ever hear of the cohort of concern?

A. Yes.

Q. When did you first hear of

the cohort of concern?

A. The cohorts of concern are in M7, that's where I heard.

Q. When? When did you first learn of the cohort of concern?

MS. DAVIDSON: Objection.

THE WITNESS: As I have said earlier, when I was working on -- when I was working on drug development with -- outside of this project, this case, I had read M7.

So that goes back, you know, before I started with this project.

BY MR. SLATER:

Q. What is the cohort of concern?

A. So M7 defines -- or lists cohorts of concern, which effectively lists a different set of types of products or compounds and says, these are of concern.

There is a, you know --

Q. What is the cohort of concern? What substances comprise the cohort of concern?

MS. DAVIDSON: Objection.

BY MR. SLATER:

Q. Do you know?

A. I would appreciate if you could show me M7, and I will direct you to it.

Q. I don't have M7 at my fingertips.

A. I don't have the list learned by heart either.

Q. N-nitroso compounds are part of the cohort of concern, correct?

MS. DAVIDSON: Objection.

THE WITNESS: Again, this is not something I have learned by heart. I would really appreciate if we could look at M7.

BY MR. SLATER:

Q. You don't know, as you sit here right now without looking at M7, whether N-nitroso compounds are part of

the cohort of concern?

MS. DAVIDSON: Objection. Badgering the witness.

THE WITNESS: I am --

MS. DAVIDSON: Please don't interrupt me, Dr. Afnan.

If you would like to pull up M7, that is permissible in this deposition, as Adam told his own witnesses.

THE WITNESS: Okay.

BY MR. SLATER:

Q. Is the answer you can't answer the question without seeing M7?

MS. DAVIDSON: Objection. Mischaracterizes his testimony. Badgering the witness.

BY MR. SLATER:

Q. I need to know, Doctor.

Are you telling me that without looking at M7 you can't tell me if N-nitroso compounds are part of the cohort of concern?

MS. DAVIDSON: Same

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objections.
THE WITNESS: So my response is delayed or not given to you.
The reason I'm asking for M7 is because you're using a very specific phrase, "N-nitroso compounds." I would like to see if M7 says N-nitroso compounds.
BY MR. SLATER:
Q. Do you -- do you know what NDMA is?
A. Yes.
Q. What is NDMA?
A. Nitrosodimethylamine.
Q. Do you know -- do you know what NDEA is?
MS. DAVIDSON: I'm sorry. Objection. When you say what it is, are you asking him what the abbreviation stands for or what it is? I think the question is vague.
BY MR. SLATER:
Q. Do you know what NDEA is?

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MS. DAVIDSON: So I'm going to have to have the same objection if you don't want to clarify the question.
THE WITNESS: It stands for nitrosodiethylamine.
BY MR. SLATER:
Q. Are NDMA and NDEA N-nitroso compounds?
A. Yes.
Q. Does the threshold approach to impurities apply to NDMA and NDEA?
MS. DAVIDSON: Objection. Are you asking -- can you repeat the question, madam court reporter?
BY MR. SLATER:
Q. Sure.
Does the threshold approach to impurities apply to NDMA and NDEA?
MS. DAVIDSON: So you're asking currently? Is that a present-tense question?
Q. During the time --

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MS. DAVIDSON: Otherwise I'm going to object as vague.
MR. SLATER: Okay.
BY MR. SLATER:
Q. During the time that ZHP developed and manufactured valsartan API, did the threshold approach to impurities apply to NDMA and NDEA?
A. Your question is based on today, looking back at 2000 -- you know, prior to 2018.
So to actually look at cohorts of concern, M7, I think, based on my recollection, is that an assessment needs to be done of the process to see whether nitroso compounds would be formed. And if there is no -- if the conclusion is that no mutagenic compounds are formed, then the unknown impurities will remain unknown.
ICH Q3A is also on the side of -- you know, parallel to M7, not on the side, parallel to M7. And ICH Q3A, at that time, and even today, says

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certain impurities can be below the threshold limit, and below .1 percent you can have unknown -- undefined, uncharacterized impurities.
Q. One of the things ZHP was required to do was to assess its manufacturing process for valsartan API, correct?
A. It was, yes. And it did.
Q. Why did you add the part about "and it did"?
A. Because -- because it did.
Q. But did I ask you if they did or not?
A. No.
MS. DAVIDSON: Objection. I don't know if that's actually a question you're asking in a deposition. That's -- you're obviously badgering the witness.
MR. SLATER: I don't think I am. What I'm doing is trying to -- I'm trying to determine the witness's understanding of my

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questions. And I'm trying to understand why it is he said they did, when I didn't ask the question.

So I'm trying to understand why he said it when I didn't ask the question about whether they did it or not.

MS. DAVIDSON: Okay. I don't think you're really trying to understand that. This is Dr. Afnan's first deposition, as he indicated at the beginning of the deposition.

So I think let's just give the man a break and move on with actual questioning.

MR. SLATER: Right. We're here to give ZHP and their expert witness on GMP a break today.

MS. DAVIDSON: I don't know what that means.

BY MR. SLATER:

Q. ZHP was required to

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assess -- rephrase.

When ZHP changed the manufacturing process for valsartan, did they need to understand the properties of the chemicals and substances that they were introducing to the process?

MS. DAVIDSON: Objection. Vague.

THE WITNESS: Can you please let me know what you mean by "properties" of substances?

BY MR. SLATER:

Q. Their function, their benefits to the process, potentially, and their potential risks as being introduced into the process as well.

Did they need to assess those things?

A. Yes.

Q. One of the things that that assessment needed to involve was the potential risk of introduction of impurities into the product, correct?

A. Can you read that question back to me, please?

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Q. I'll ask it again. I'll try to be even clearer.

A. Sure.

Q. In terms of assessing the risks of introduction of a chemical or a substance to the manufacturing process, one of the risks that needed to be assessed was whether that chemical or substance would introduce impurities into the process, correct?

A. Yes.

Q. And that assessment is expected to be or required by cGMP to be a scientific assessment, correct?

A. Can you tell me what you mean by "scientific"?

Q. The assessment needs -- rephrase.

The assessment needed to be based on scientific information that was available to those people who were in charge of this process, for example, information that was available in the

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scientific literature, correct?

A. So the way they would be expected and the way which is current practice, and was practice at that time, was for the firm to look at the process, to look at the raw materials that it was buying, making sure that those materials met specifications; and then look at the process and assess whether an undesired side reaction will take place.

If those did not take place, then there would not be a logical reason for -- a scientific reason for going and trolling through the scientific community to see what else would happen.

So it is a -- it isn't a black-and-white, you know what, they should have -- they should have looked at everything in the scientific community, because that's not logical.

Q. Before ZHP introduced a new substance into the manufacturing process, it needed to understand -- well, let me walk back, actually.

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One of the things you said is that they must look at the raw materials it was buying and make sure they meet the specifications; is that one of the things you said?
A. They -- industry generally requires to qualify its vendors.
Q. What does it mean to qualify a vendor?
A. To look at a vendor, to make sure that the vendor has acceptable GMPs, and the substance which is coming in, there are specifications, and those specifications can be met.
Q. In terms of understanding the specifications for the substances that are being purchased from vendors, that would include, for example, if a solvent was being purchased for use in a manufacturing process, correct?
A. Sorry, can you repeat the question?
Q. Sure.
When you talk about looking

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at the specifications for the substances that are being purchased from vendors, that would include, for example, if the manufacturer purchased a solvent to be used in the manufacturing process, correct?
A. So there is a qualification to my response, which is defined in ICH Q7. ICH Q7 categorizes intermediates and raw materials which are purchased for use in an API process.
And that effectively depends whether that solvent is expected to remain in the process or whether it will be removed from the process during processing.
So as you get closer to that solvent remaining in the process, they -- the regulatory requirement or the GMP requirement goes up.
Q. When you say if that solvent remains in the process, you're not saying it has to remain so long that it ends up in the finished drug -- in the finished

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API product, are you?
MS. DAVIDSON: Objection.
BY MR. SLATER:
Q. Is that what you mean, that staying in the process means it ends up -- that that solvent is a part of the finished API that comes out of the process?
MR. SLATER: I just want to understand what the doctor is saying.
MS. DAVIDSON: Objection. You asked a question and I objected. And then you asked a new question, and now I don't know which of the two questions is pending.
If you changed your first question to the second question, I object to the second question.
BY MR. SLATER:
Q. When you refer to the process -- rephrase.
When you refer to the

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substance, in this case we're talking about a solvent, remaining in the process, are you saying remaining in the process until the end so that the solvent is actually in the API product that is yielded by the process?
MS. DAVIDSON: Objection.
THE WITNESS: So the way the regulations work, the way the GMPs work, if you get a solvent which is used in your processing, the question that comes up that needs to be taken into consideration by the firm is whether the downstream processing steps would effectively remove that solvent from the process.
However, in industrial setting productions, it is extremely rare for all the solvents to be removed from the process. And for that reason, most of the solvents which are used in industry all have an

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allowable limit in the API, in the finished API.
BY MR. SLATER:
Q. Does ICH Q7 require that when ZHP purchased, for example, DMF from a supplier, that it would either test the DMF to see what it contained or rely on the supplier's certificate of analysis for that DMF to know what the DMF contained?
MS. DAVIDSON: Objection.
THE WITNESS: So Q7 doesn't address ZHP at all. Q7 addresses the what-to-do of pharma for APIs.
Again, if I look at Q7, Q7 would require the quality unit -- a part of Q7 would require that the solvent supplier be qualified, that the solvent supplier sell, your example of DMF, dimethylformamide, and that dimethylformamide would have a specification which is provided by the firm. And the C of A is

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provided with every batch. According to current practice, or good manufacturing practice, the customer -- you know, a customer, a manufacturer, an API manufacturer, would qualify that solvent, number one, and then it would do IE testing of the batches throughout the year. And at least one batch would be fully tested, as per the C of A. So if there are five tests on the C of A, those five tests would be run by the API manufacturers.
BY MR. SLATER:
Q. When you say they test per the C of A, is that to compare what their tests show versus what the certificate of analysis shows should be within the substance?
A. Yes.
Q. Do you know whether ZHP ever looked at the certificate of analysis for the DMF that it purchased and used in the

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zinc chloride process?
MS. DAVIDSON: Objection.
THE WITNESS: According to FDA inspections of ZHP and, in particular, the 2018 for-cause inspection where the inspector says there is a quality unit which is well established, I would conclude, based on that, that ZHP would have been testing materials coming in and would have had met the regulatory requirements.
Because during the for-cause inspection, the investigator says their quality and it is established it is operating well. Previous inspections also found that the quality unit was functioning properly.
BY MR. SLATER:
Q. So that I understand -- let me just take a step back.
The reason I'm asking some of these questions, so you know where I'm

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going is, you're coming in as an expert to try to give opinions. You didn't live through this, so you have to have your own understanding of the facts, based on the materials provided to you.
You looked at a lot of documents, you looked at testimony, you looked at various things in order to understand what you think the facts are, right?
MS. DAVIDSON: Objection. I don't know if that was actually a question or --
MR. SLATER: I'll ask another question, because I don't want to dismay you.
BY MR. SLATER:
Q. Doctor, did you draw certain factual assumptions in order to then form opinions?
MS. DAVIDSON: Objection.
THE WITNESS: Can you rephrase or repeat the question?
BY MR. SLATER:

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Q. Sure.
In order to form the opinions you formed in this case, did you rely on certain factual assumptions so that you said to yourself, okay, the facts are this, so based on these facts, my opinion is this?
MS. DAVIDSON: Objection.
BY MR. SLATER:
Q. Did you do that as part of your methodology here?
MS. DAVIDSON: Objection. I think when you ask one question, let's stop at that question, have the objection, have an answer.
Because we have this pattern where I object and then you have, like, a follow-up question. I think it's creating a very unclear record.
THE WITNESS: So the scope of my work was to assess whether they followed the GMPs specifically in relation to the

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issues here and specifically in relation to plaintiffs' expert reports, which have been submitted.
None of the expert reports -- the plaintiffs' expert reports, question the C of A or the solvent purchased by DMF.
So did I have certain assumptions? My point is, I am a GMP assessor in this case, and I'm looking to see whether ZHP adhered to the GMPs or not.
And in the same way an inspector would go on site and make conclusions and draw conclusions, I am relying on what I call facts that the inspector writes in her EIR and in her observations.
BY MR. SLATER:
Q. So one of the assumptions that you drew in this case is that ZHP looked at the certificates of analysis

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for the DMF it purchased for use in the zinc chloride process; do I understand you correctly?
A. So, first of all, it's a solvent that is added to the process and then removed from the process, based on the process description that ZHP gives.
That makes it a low-risk, low-category ingredient going into the process, number one.
Number two, did I draw any conclusions that they must have looked at the C of A? And the answer is, if they did not, if they had not released their DMF, their solvents, they would have been cited over and over and over.
Q. Is it your understanding, in forming your opinions, that ZHP looked at the certificates of analysis for the DMF it purchased for use in the zinc chloride process; yes or no?
MS. DAVIDSON: Objection.
THE WITNESS: ZHP looked at the C of As of the DMF it

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purchased.
BY MR. SLATER:
Q. Did you ever look at any certificate of analysis in connection with the DMF that was purchased by ZHP and used in the zinc chloride process?
I just want to know if you ever saw any certificate of analysis for that DMF.
COURT REPORTER: Ms. Davidson, you're on mute.
MS. DAVIDSON: Sorry about that. I was objecting.
I'm glad you can read lips.
THE WITNESS: So ZHP, in its investigation that it sent to FDA, lists the DMF suppliers and the quality of those DMF supplies.
Now, did I look at the specific C of A? I honestly do not recall.
BY MR. SLATER:
Q. That's all I asked you.
I just asked you if you saw

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any certificate of analysis for the DMF.
MS. DAVIDSON: Objection. I don't know if that's a question or --
BY MR. SLATER:
Q. So the point is, you don't recall, correct?
MS. DAVIDSON: Objection. Asked and answered.
THE WITNESS: I looked at the data that was presented to FDA, which FDA accepted. That, I do remember.
I do not remember specifically looking at the C of A of DMF.
MR. SLATER: We're going to put up an exhibit. For purposes of this deposition, I think this is Exhibit 5 or 6. This is Exhibit-5.
- - -
(Whereupon, Exhibit Afnan-5, PRINSTON00075810-6099, Deviation

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Investigation Report, was marked for identification.)
- - -
BY MR. SLATER:
Q. So to be clear, Exhibit-5 on the screen is the deviation investigation report, which was actually marked at a prior deposition Peng Dong as ZHP 210.
Do you see that document on the screen?
A. I see it. I would appreciate it if it could also be put into the share folder.
Q. It's there.
A. Okay. Thank you.
Q. Have you seen this document before?
A. That is the investigation I was referring to.
Q. Was this a document that was significant to you in evaluating this case and forming your opinions?
MS. DAVIDSON: Objection.
THE WITNESS: This was one

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of the documents that was of significance to me.
BY MR. SLATER:
Q. Let's go to Page 7 of 236 of this document, please. I'm looking at the bottom part of the page.
This states, Based on the investigation and the evaluation of the current valsartan route of synthesis (zinc chloride process), this impurity is most likely formed during the azide quenching by nitric acid of the API manufacturing process.
Do you see where I'm reading under Figure 3.1, which says, The structure of NDMA? Do you see where I'm reading?
A. Yes.
Q. Continuing, it says, Specifically, dimethylformamide (DMF) one of the solvents used in Step 4 (Crude) stage, may contain trace amount of dimethylamine as an impurity. Furthermore, during the tetrazole

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formation step, dimethylformamide may be susceptible to low-level decomposition under high temperature to produce trace amount of dimethylamine, either by thermo decomposition or hydrolysis.
Do you see where I just read?
A. Yes.
Q. Did you read that language as part of your evaluation of this case in forming your opinions?
A. Yes.
Q. So when you formed your opinions in this case, you were aware that dimethylamine could be introduced -- rephrase.
So when you formed your opinions in this case, you understood that ZHP had determined that the DMF that it was using in the zinc chloride process may contain a trace amount of dimethylamine as an impurity before it even was added to the process; you had read that language and understood it when

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you formed your opinions, correct?
MS. DAVIDSON: Objection.
THE WITNESS: So what is interesting is, what is the date of this document? Can you go to the top or the bottom, or wherever, and tell me what's the date of that document?
MS. DAVIDSON: I believe, Dr. Afnan, if it was placed in the --
MR. SLATER: It's November 5, 2018.
BY MR. SLATER:
Q. Please answer the question.
MS. DAVIDSON: Adam, you interrupted me.
Dr. Afnan, I believe if a document has been placed in the share drive, or whatever it's called, as Adam noted, that you can move up and down on it yourself.
You can open it; is that

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correct?
THE WITNESS: Yes.
MS. DAVIDSON: I just wanted to clarify that.
THE WITNESS: Thank you.
So this was an investigation taking place -- in fact, this was Version Number 2, as it says on the screen.
This was an investigation which was taking place where ZHP was trying to find the root cause and the method of formation of NDMA in the process.
This is not a statement about, you know what, this is what we did. They are testing every single possible pathway to formation of NDMA. This document is being written with a 20/20 hindsight that NDMA was present in valsartan. And as requested and required by their system and FDA, they're digging into where is this

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NDMA coming from.
BY MR. SLATER:
Q. My question was simply whether you took that information that I just read with you into consideration when you formed your opinions.
It's a yes-or-no question. I just want to know if you took it into account when you formed your opinions.
MS. DAVIDSON: Objection. Again, I'm going to have to object every time you say it's a yes-or-no question.
THE WITNESS: I actually do not believe I can give you a yes-or-no answer.
So if -- again, you know, FDA said -- Dr. Gottlieb, on the 30th of August, 2018, says, because it was not anticipated that NDMA would occur at these levels in the manufacture of the valsartan API, manufacturers would not have been testing for it.

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That's what FDA said.
BY MR. SLATER:
Q. Can you just answer my question, please?
A. I did. I can't give you a yes-or-no answer.
Would you like to rephrase your question?
Q. You told me a moment ago that you read this language when you were preparing your report, correct?
A. Yes.
Q. So you knew this information when you wrote your report, correct?
MS. DAVIDSON: Objection.
THE WITNESS: I had to take everything that I read in the context of why, when, how, and why am I reading it.
Again, this is a 20/20 hindsight in 2018, back end of 2018, where ZHP is making -- effectively trying to make NDMA. And this is the report of them

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trying, trying, to make NDMA. So they write this report when they are trying to make NDMA.

So did I read this when I -- before writing my report? Yes, the answer is, I read this before I wrote my report.

BY MR. SLATER:

Q. Having read this, did you consider the possibility that dimethylamine was introduced to the zinc chloride process as an impurity of DMF?

Did you consider that as one of the pathways by which the NDMA got into the process; yes or no?

MS. DAVIDSON: Objection. I think that's --

THE WITNESS: Again, the scope of my work was to look at the plaintiff experts reports and assess that, as well as the GMP assessment. My scope was not to dig into the chemistry of the formation of NDMAs.

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And, again, I'll repeat, this report is a look-back after ZHP knew NDMA had been formed, and they were now looking at the pathways of formation of NDMA.

This is after -- this report, this language, is after the language by Scott Gottlieb, FDA commissioner, which said it was not anticipated that NDMA would occur at these levels in the manufacture of the valsartan APIs and manufacturers were not testing for it.

BY MR. SLATER:

Q. In forming your opinions, did you consider the possibility that the dimethylamine was introduced to the zinc chloride process as an impurity of DMF as the DMF was purchased?

A. So there is no monograph for DMF that I have been able to find. There are specifications for levels of DMF in finished APIs which effectively indicate,

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to me -- indicated, to me, that DMF, which is a very common solvent, actually, in the pharma industry, that if it's used it would have followed certain -- certain common practices, certain behaviors, you know, certain practices that were practiced across industry.

And, again, your question of could this have come with DMF, the answer goes back to, this text that you're showing me is -- is a hypothesis of this could have come -- it's a hypothesis that this could have come.

As it says, it's most likely formed during the azide quenching by nitrous acid of the API. One of the solvents used and inspected for may contain trace amounts of dimethylamine as an impurity.

Q. You just said that because DMF was a very common solvent you would expect that there would be certain familiarity with DMF within the industry and that certain common practices would

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be followed.

Can you tell me, first of all -- well, let me rephrase the question.

Do you have an opinion as to what, as a matter of GMP, the people at ZHP should have understood about the potential impurities within DMF when they decided to use that solvent in the zinc chloride process?

MS. DAVIDSON: Objection.

THE WITNESS: Can you either repeat or rephrase, please?

BY MR. SLATER:

Q. Sure. I'll rephrase it. I'm actually going to ask it differently.

When you referred a moment ago to certain practices in the industry, what specific practices, with regard to DMF, are you aware of that you would expect ZHP followed?

A. So industry --

Q. I'm not asking -- by the way, just to be clear, I'm not asking

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generally. I'm asking with regard to DMF.
MS. DAVIDSON: Why don't you just rephrase it, then? Because --
MR. SLATER: I don't think I need to.
MS. DAVIDSON: We need clear questions.
MR. SLATER: Thank you for telling me my questions aren't clear.
BY MR. SLATER:
Q. Please answer, Doctor.
MS. DAVIDSON: I'm sorry, but you added a caveat after your question. At this point, I don't even know what the standing question is.
So I'm going to --
MR. SLATER: That's good because you're not the one who I'm actually deposing. So we're good.
MS. DAVIDSON: Adam, thank

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you. I object to your question as vague and --
MR. SLATER: I'll ask again, because you're going to -- you're going to have this conversation with me, and it's not going to really get us anywhere.
So I'll ask it again, Doctor.
BY MR. SLATER:
Q. What practices in the industry would you expect that ZHP followed with regard to the DMF that it purchased and used in the zinc chloride process?
A. ZHP would have -- ZHP would have effectively selected a supplier. ZHP would have signed an agreement with them. ZHP would have received a specification from them. ZHP would have then effectively developed the same analytical methods or similar analytical methods as them. ZHP would have effectively looked for how this solvent

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would remain in the process. And ZHP would have, at the beginning, when they were developing the process and follow-on, they would have used USP standards for residual solvents.
Q. When you say the spec would be received, is that the certificate of analysis?
A. The specification without being listed on the C of A, maybe.
Normally, the informations are communicated separate from the C of A. And a C of A would have been submitted as part of the specifications.
Q. You said something a few moments ago about whether there was a monograph for DMF.
If there was a monograph for DMF, would you expect that ZHP would have looked at the monograph to get information about the DMF?
MS. DAVIDSON: Objection.
THE WITNESS: I'm struggling with ZHP getting information from

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the monograph.
Could you please explain your question -- that question to me?
BY MR. SLATER:
Q. Sure.
A. I apologize.
Q. Sure.
You said just a few moments ago that you're not aware of a monograph for DMF.
Did I understand you correctly when you said that a few minutes ago?
A. Yes.
Q. Okay. All right.
MR. SLATER: We're going to put up a new exhibit, which is going to be Exhibit-6.
- - -
(Whereupon, Exhibit Afnan-6, No Bates, Concise International Chemical Assessment Document 31, was marked for identification.)

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- - -
BY MR. SLATER:
Q. This is a World Health Organization document from 2001.
And as you can see, it's titled, N,N-dimethylformamide.
Do you see that on the screen?
A. Yes.
Q. I assume you've not seen this before, based on the answer you gave me a couple of questions ago that you had not seen a monograph about DMF; is that correct?
A. That's incorrect. I have seen this. That's not a monograph.
Q. Okay. So let me -- let me start over.
You've seen this document?
A. Yes.
Q. When did you see it?
A. During the course of my reviews before writing my report.
Q. Let's go to Page 5.

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Looking at the bottom right corner, the first full paragraph under Section 2, titled, Identity and Physical/Chemical Properties.
Do you see where I am on the bottom right?
A. Yes.
Q. The first paragraph under that heading, the last sentence says, DMF sold commercially contains trace amounts of methanol, water, formic acid and dimethylamine.
And then there's a citation to a publication from 1994.
Do you see that?
A. Yes.
Q. Did you see that when you wrote your report?
A. As I said, I have seen the report, yes. I've seen this document. Yes.
Q. So you knew when you wrote your report that according to a World Health Organization publication about

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DMF, dated in 2001, the impurities of DMF sold commercially include dimethylamine? You would have seen that and known that when you wrote your report, correct?
MS. DAVIDSON: Objection. That's not what he said.
THE WITNESS: Can you rephrase, please, or repeat?
BY MR. SLATER:
Q. When you wrote your report --
A. Yes.
Q. -- you were aware that this publication stated that DMF sold commercially contains dimethylamine? You knew that when you wrote your report, right?
MS. DAVIDSON: Objection.
THE WITNESS: So here is my response, right. This is a general statement about DMF. The challenge is going to be multiple-fold.
One is, was there a USP or

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EP monograph for DMF? And the answer is still no.
Did, effectively, every batch of product they manufactured have dimethylamine because of this statement? That's a conclusion that cannot be drawn.
Even if it is there, again, if this is available to ZHP, then why would the FDA say that neither industry nor regulators knew about the formation of NDMAs?
BY MR. SLATER:
Q. If ZHP had looked at scientific literature and read this document and seen that commercially sold DMF contains trace amounts of dimethylamine, they would have been on notice of the potential for dimethylamine to be introduced to the zinc chloride process as an impurity of the DMF they were purchasing; they would have been aware of that possibility, correct?
MS. DAVIDSON: Objection.

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THE WITNESS: ZHP considered their process, looked at their materials, looked at what they were doing and assessed the process for unknown impurities which would cause problems, unknown impurities which would be mutagenic. And they came to the conclusion, based on the information they had, that that was not the case.

So saying because of this document they should have known about dimethylamine, I don't know how that relates to assessment of the -- risk assessment of the manufacturing process. Because, again, this is not a document that one would go to if you are not manufacturing for WHO regions.

MS. DAVIDSON: Is this a good time for a break?

THE WITNESS: Yes.

MR. SLATER: It's not,

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actually, because I have to do something at noon, so I'd rather go another ten minutes and then take a break at noon. I have to speak to somebody for about ten minutes.

MS. DAVIDSON: Noon is in 16 minutes, actually.

MR. SLATER: I realize. I don't need to stop exactly at noon, but thank you for correcting my time count.

MS. DAVIDSON: Dr. Afnan, would you like a break now or wait until noon?

THE WITNESS: I would --

MR. SLATER: We can't go for ten more minutes? I mean, come on.

MS. DAVIDSON: I'm asking the witness.

THE WITNESS: I would appreciate it, because my mouth is really dry and I need to drink

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something.

MS. DAVIDSON: Okay. Let's go off the record.

MR. SLATER: You don't have any water with you, Doctor?

THE WITNESS: I've run out.

MS. DAVIDSON: I'm sorry. I'm sorry. No, we're not doing this.

MR. SLATER: You don't need to be so angry. It's not necessary to be so angry.

MS. DAVIDSON: I'm not angry, Adam. I think you're the one who is angry.

Let's take a seven-minute break, and then we can do a few minutes before your noon call.

Let's go off the record.

VIDEO TECHNICIAN: We're off the record at 11:45 a.m.

- - -

(Whereupon, a brief recess was taken.)

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- - -

VIDEO TECHNICIAN: We're back on the record at 11:54 a.m.

BY MR. SLATER:

Q. In evaluating this case -- actually, let me -- let me withdraw that.

MR. SLATER: Do you have that document ready? Let's go to the next exhibit, which is Exhibit-7.

- - -

(Whereupon, Exhibit Afnan-7, No Bates, Dimethylformamide: Purification, Tests for Purity and Physical Properties, was marked for identification.)

- - -

BY MR. SLATER:

Q. On the screen is Exhibit-7, a publication of the International Union of Pure and Applied Chemistry, titled, Dimethylformamide: Purification, Tests for Purity and Physical Properties.

Do you see that?

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A. Yes.
Q. Have you ever seen this document?
A. I do not recall. I don't think so, but I don't recall.
Q. Let's go to Page 887, please, the middle of the page.
You see in the middle of the page there's two formulas? Just below the first formula, do you see the word "formic acid"?
A. Yes.
Q. Looking at the middle of the page it says, Formic acid and dimethylamine are thus predominant impurities in DMF and determine the odor of the impure solvent.
Do you see that?
A. Yes.
Q. So this would be another publication, and just for the record, this publication is from 1977, stating that dimethylamine is a -- one of the predominant impurities in DMF.

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That's what this says, right?
A. Those are the words on the screen.
Q. Based on the literature I've shown you, would you agree with me that ZHP should have been aware that the DMF they were using in the zinc chloride process could contain dimethylamine as an impurity and could introduce the DMA to the process as an impurity of the DMF?
Do you agree that ZHP should have been aware of that possibility?
MS. DAVIDSON: I object. This is outside the scope of his opinions. He's not a chemist here.
MR. SLATER: I'm not asking a chemistry question.
BY MR. SLATER:
Q. I'm asking, from a GMP perspective, should ZHP have been aware of the potential introduction of the dimethylamine to the zinc chloride process as an impurity of DMF?
MS. DAVIDSON: Based on the two lines you read?
MR. SLATER: I'm not going to go back-and-forth with you.
BY MR. SLATER:
Q. Please answer the question.
A. So ZHP investigated the process with DMF and zinc chloride for two years, okay? This was reported to FDA, as well, after doing their research.
So based on the work they did, based on the data, and based on the verification review by FDA, and their drug product manufacturing clients, the question of should they have known or not, the question of did they know about the formation of NDMA, and the answer is they did not know.
FDA also states that they did not know. FDA says they do not know, nor did industry, knew where these were coming from.
Q. As a matter of GMP, was ZHP

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to understand -- rephrase.
As a matter of current good manufacturing practices during the development and use of the zinc chloride process, was ZHP obligated, as a matter of cGMP, to be aware that one of the known impurities of commercially sold DMF was dimethylamine?
Were they -- were they required to at least be aware of that fact in performing their risk assessment; yes or no?
MS. DAVIDSON: Objection. Lacks foundation.
THE WITNESS: ZHP would not be looking at the research based on publications. They would have been looking at the research based on what was happening in the chemistry, in their -- in the reactors, and the analytical results they were getting, and also based on the documentation they were receiving from their

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suppliers. All of that was then run by FDA.

So to say that here is a statement and because of this they should have taken that into consideration, I think it's a -- it's an extrapolation of this to something else that was not there.

ZHP looked at, effectively, the process, they developed it. They took two years. They ran multiple samples. They did extensive testing. Then they decided to change the process, which was then submitted to both FDA as well as EDQM, the European authority.

BY MR. SLATER:

Q. I just want to be clear.

It's your opinion that ZHP, as part of its risk assessment, did not need to consult scientific literature at all with regard to potential risks of the substances they were using in their

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manufacturing processes for valsartan?

MS. DAVIDSON: I'm going to object that that mischaracterizes his testimony. And it may be that you're mischaracterizing his testimony, because while he was answering you were --

MR. SLATER: I don't know why you're giving a speech. You objected, I --

MS. DAVIDSON: -- engaged in another conversation and not looking at the camera and listening to his answer.

And that may be why you misheard it.

MR. SLATER: Counsel, please don't make any more speaking objections today.

BY MR. SLATER:

Q. Can you answer the question, please?

A. So, again, to repeat my answer -- to repeat my answer, ZHP looked

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at its chemical manufacturing process of zinc chloride and DMF as a catalyst and a solvent. ZHP took two years to develop that process. ZHP extensively tested that process and the products from that process. ZHP used the methodology -- the analytical methodology that was available to it. Documented it all, then submitted it to FDA.

ZHP even made an engineering batch of -- of valsartan with the new process, submitted all of that to FDA.

So with that body of evidence versus going and looking specifically in the universe of published literature for dimethylamine is not logical. So did they investigate? They did investigate.

Q. And you agree with me, based on the testimony you've read and the stipulation you've read that was entered in this case, ZHP did not do scientific research in the literature with regard to potential impurities or degradation of

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DMF, correct?

MS. DAVIDSON: Objection.

BY MR. SLATER:

Q. I understand you're saying they didn't need to do it.

I'm just asking if you agree they did not do it?

MS. DAVIDSON: Objection.

THE WITNESS: I didn't say they didn't need to do it. You're mischaracterizing what I said.

My statement, again, is that they did do sufficient risk assessments, sufficient assessment of the process, the zinc chloride process, before compiling the data and submitting it to the regulator.

MR. SLATER: Let's go off the record.

VIDEO TECHNICIAN: We're off the record at 12:04 p.m.

- - -

(Whereupon, a luncheon

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recess was taken.)

- - -

VIDEO TECHNICIAN: We're back on the record at 12:44 p.m.

BY MR. SLATER:

Q. You mentioned at one point that you were retained to respond to the plaintiff experts.

Do you remember you told me that earlier?

A. They -- the scope of my assignment was to effectively opine on the subjects which are -- or the topics which are raised against ZHP, yes.

Q. And did you understand your role to be to, in essence, defend ZHP against these accusations?

MS. DAVIDSON: I'm sorry, I was on mute.

I'm objecting to that question.

Court reporter, can you read that question back?

- - -

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(Whereupon, the court reporter read the following part of the record:

"Question: And did you understand your role to be to, in essence, defend ZHP against these accusations?")

- - -

MS. DAVIDSON: Yeah, that's a very objectionable question. So I'm doubling my objection.

MR. SLATER: I'll ask the question differently.

BY MR. SLATER:

Q. Did you understand your role to be to come up with arguments to defend ZHP?

MS. DAVIDSON: Same objections.

THE WITNESS: That was not how I have approached this.

My approach to this is, there are statements made by plaintiff experts, assess them

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for -- for correctness. And, at the same time, look at the -- you know, see what is being said and whether there is -- whether that is correct or not. Yeah.

BY MR. SLATER:

Q. Let's go back to the document that we had up before. We're back in Exhibit-7 now.

Looking at Page 887, where it says, Formic acid and dimethylamine are, thus, predominant impurities in DMF and determine the odor of the impure solvent.

My question is, do you understand what that means when this document and this publication says that dimethylamine is a predominant impurity in DMF? Do you understand what that means?

MS. DAVIDSON: Objection.

THE WITNESS: How is "predominant" qualified?

BY MR. SLATER:

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Q. You see the words on the page, I'm asking if you understand what that means.

A. Okay. So I'm looking at the word "predominant impurities," and I would want to know what sort of a percentage impurity that is.

Q. Why does that matter?

A. So there are no 100 percent pure compounds in manufacturing grade and, therefore, it is relevant because it's a case of -- this is a -- this is a scientific hypothetical statement, that when you make this with this you have two impurities or two of the degradation products; the thermo degradation produces this and this.

What is lacking in the statement and, respectfully, in your question, there is no information about what the thermal conditions are, nor about what the percentages or what the levels of those two degradation products are.

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Q. Was ZHP required to assess the potential risks of potential impurities that could be introduced to the manufacturing process by the substances that ZHP was using?
A. Can you repeat, please?
Q. Was ZHP supposed to assess the potential risks from the potential impurities that could be introduced to the valsartan manufacturing process?
We're talking about the zinc chloride process here. Let's talk about that.
A. So ZHP, as per practice and regulations, would have been looking and would have needed to demonstrate looking for potential impurity formations. And, effectively, they would have needed to validate it, which they did.
And then submit it to the regulator, which they did. And the regulator agreed with their assessment at the time.
So what they were supposed

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to do they did do, and the regulator agreed with that assessment.
Q. So you agree that ZHP was required, as part of its assessment, to assess the potential risks from the potential impurities that could be introduced to the zinc chloride process from the substances that were being used; you agree with that, correct?
MS. DAVIDSON: Objection.
THE WITNESS: I responded to that. I don't know how to respond again.
BY MR. SLATER:
Q. Well, you did, Doctor, just what I heard was you told me what they did and what regulators did. And I literally did not ask you about what anyone else did. I asked what would they do. I asked what they were supposed to do.
I just want to know if they were supposed to look at that or not?
MS. DAVIDSON: Okay. So

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first of all --
MR. SLATER: I don't need a lecture. You can object to the question. You have an objection to form. He can answer.
You are not allowed to give a speaking objection. Please don't.
MS. DAVIDSON: Adam, you have given speaking objections endlessly in the last two weeks.
MR. SLATER: I'm asking you to not to do another speaking objection. Can you just please let him answer the question?
MS. DAVIDSON: No. No. Because, Adam --
MR. SLATER: So don't let him answer. You're going to give a speech. Go ahead. Give a speech.
MS. DAVIDSON: Adam, you interrupted Dr. Afnan. And as you know, that is not appropriate

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deposition behavior. Then when I tried to explain that you were interrupting Dr. Afnan, you proceeded to interrupt me. So you've now interrupted both of us in the course of this. I was not appreciative of that.
Please allow the witness to finish answering questions he's asked. Please do not interrupt him.
I would object if there were a question pending, but I don't even know what question is pending now. Because, basically, the witness started to answer the question and you berated -- interrupted and berated him.
So why don't we have the court reporter read back the question, and why doesn't Dr. Afnan provide a complete answer?
MR. SLATER: I'm not going

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to -- I'm going to ask the question again myself.
BY MR. SLATER:
Q. So, Dr. Afnan, do you agree that ZHP was required to assess the potential risks from the potential impurities that could be introduced to the zinc chloride process by the substances that ZHP was using; yes or no?
A. ZHP did do that. So yes. But they did do that.
Q. I didn't ask if they did it. I asked if they were supposed to do that.
Can you just answer that question, please?
A. I did answer.
MS. DAVIDSON: Objection. Objection. Asked and answered.
BY MR. SLATER:
Q. Doctor, I would appreciate --
MS. DAVIDSON: You cannot control the way he answers a question. You can't, like, tell

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him to repeat his question and cut off half the answer. Come on.
BY MR. SLATER:
Q. Doctor, I'm not asking you what ZHP actually did.
I asked you if they were supposed to evaluate the potential risks from the potential impurities that could be introduced to the zinc chloride process by the substances that ZHP was using.
I just want to know if that's something they were supposed to do. I'm not asking if they did it or not.
Can you please answer that question?
MS. DAVIDSON: Objection. Compound. And asked and answered.
THE WITNESS: ZHP did what it was supposed to do.
BY MR. SLATER:
Q. I'm sorry. Can you answer my question, please?

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A. I did.
Q. I'm not asking you what ZHP did. So I'm not sure why you're insisting on continually saying what ZHP did.
I asked what they were supposed to do. I didn't ask if they did it or not.
So can you please answer my question?
MS. DAVIDSON: I'm going to object again. Asked and answered. Compound question. Badgering the witness.
THE WITNESS: ZHP did what it was supposed to do.
BY MR. SLATER:
Q. Please answer my question.
I'm not asking what ZHP did.
Can you please answer my question about what they were supposed to do?
MS. DAVIDSON: Objection. We can stay on this all day if you

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want. It's been asked and answered multiple times.
THE WITNESS: Yep. Yep.
BY MR. SLATER:
Q. I'm sorry, Doctor, that doesn't substitute for your answer. Just because counsel keeps talking and saying things. You have to actually answer the questions, under oath, yourself.
A. I answered the question that was asked, Mr. Slater.
My answer to you was ZHP followed the regulations, followed the GMPs, which sets the expectations, and carried out those activities.
Q. I keep telling you I'm not asking what ZHP did. I don't know why you keep telling me what ZHP did.
Am I not communicating clearly?
MS. DAVIDSON: Objection. I'm going to instruct you not to answer that question. That is not -- that is a rhetorical

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question. You're badgering the witness.

Come on, Adam, just ask your questions and that's that. Don't badger the witness.

MR. SLATER: I don't really want to talk directly with you at this point about this. I really just want to explain to him, since it's his first deposition, that when I keep asking one question and he keeps talking about something I'm not asking, I find it to be, you know, a little bit frustrating. I'm not yelling. I'm talking in a normal tone of voice.

And I don't understand why he keeps telling me what they did when I've said, like, six times in a row, I'm not asking what they did. I'm asking what they're supposed to do.

So I'm starting -- I'm

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feeling like he won't answer my question deliberately, which doesn't feel good.

So I'll give it one last shot, and then we'll mark this part of the transcript.

BY MR. SLATER:

Q. Doctor, I'm not asking you what ZHP did. I'm asking if they were supposed to do what I asked you.

Can you just answer that question, please?

MS. DAVIDSON: Objection. Vague. Asked and answered. Mischaracterizes his testimony.

I think that's it.

THE WITNESS: Can you read back the question that you keep asking me, which I believe I have answered?

BY MR. SLATER:

Q. Here is the question: Was ZHP required to evaluate and assess the potential risks from potential impurities

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that could be introduced to the zinc chloride process by the substances that ZHP was using?

I want to know if they were supposed to do that. I'm not asking what they did. I'm asking if they were supposed to do so.

Can you please answer that question?

MS. DAVIDSON: Objection. Vague. Asked and answered.

Dr. Afnan, do you want the question read back by the court reporter?

THE WITNESS: Sure.

MR. SLATER: You need the question read back?

THE WITNESS: Yes, please.

BY MR. SLATER:

Q. Was ZHP required to assess the potential risks that could be introduced due to potential impurities from the substances used in the zinc chloride process; yes or no?

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MS. DAVIDSON: Objection. Vague. Asked and answered.

THE WITNESS: ZHP looked at the potential risks due to the potential impurities in the process, referring to the zinc chloride process, and came to a conclusion, which was reported to FDA.

ZHP did do what it was supposed to do.

BY MR. SLATER:

Q. Did I ask you what ZHP did in that question?

MS. DAVIDSON: Objection. That's not a question to answer.

MR. SLATER: It actually is a question.

BY MR. SLATER:

Q. Please answer.

MS. DAVIDSON: No.

BY MR. SLATER:

Q. Doctor, did I ask you what ZHP did or did I ask you, as I have,

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like, multiple times, asked you what they were supposed to do?
MS. DAVIDSON: Objection.
BY MR. SLATER:
Q. I mean, is my question not clear? Are you not understanding my question? If you're not then I can, you know, rephrase it.
MS. DAVIDSON: Adam, every time I object you just badger the witness more. And so I don't even know what question is pending.
And I'm objecting to your follow-on badgering of the witness following the badgering of the witness I already objected to.
THE WITNESS: You want a yes-or-no answer from me. I am not able to give you a yes-or-no answer, because I think the question has no merit of a yes-or-no answer -- or the answer has no merit if it's a yes-or-no answer.

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I believe I have answered the question multiple times in exact same manner and have addressed the question you have asked me.
BY MR. SLATER:
Q. Let's go now to Page 890 of that document. Same document we've been in, which is Exhibit-7. The very top.
At the top of Page 890, it says, Tests for purity. Owing to its various modes of degradation, hydrolysis, thermal and photochemical decomposition, the principal impurities found in DMF are: dimethylamine, formic acid, hydrogen cyanide, carbon dioxide and carbon monoxide.
Do you see that?
A. I see it, yes.
Q. In forming your opinions in this case, did you take into account the fact that DMF could degrade through hydrolysis and due to thermal impact, meaning temperature?

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Did you take that into account, that those were both pathways to degradation that could yield dimethylamine?
MS. DAVIDSON: Objection.
THE WITNESS: Dr. Xue, who is a synthesis organic chemist, a respected lecturer at University of Maryland, addresses those issues -- those points, in his testimony.
The thermal decomposition that you have asked me about and is on the screen is effectively based on reaching a particular temperature which the process was never at.
So if that temperature is not reached and if hydrolysis is not taking place, because it's neither acidic or basic, then -- the question of did I take that into account? The answer is, yes, I did take that into account.

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BY MR. SLATER:
Q. Did you form your own independent opinion about what you just told me, or were you relying on Dr. Xue's analysis of that subject matter?
A. Dr. Xue refers to two statements. One is about the boiling point of DMF, which I have referenced him and verified by looking at, effectively, the boiling point of DMF. I've also looked at the pH of the process, which, again, he refers to, and, again, I have verified.
So is it my opinion or is it his opinion? It's my opinion.
Q. And you are not an expert in the field of organic chemistry, right?
A. I am --
MS. DAVIDSON: Objection. Objection. You literally objected, Adam, last week every single time I asked somebody if they were an expert in something.
MR. SLATER: I'll ask the

question differently.
BY MR. SLATER:
Q. You told me before that you are not holding yourself out as an expert in organic chemistry.
Have you changed your mind on that?
A. I have a degree in chemistry. I have a Ph.D. in chemistry.
I am not a synthetic organic chemist and up to date, but I do understand sufficiently about chemistry to opine on the subject.
Q. In the materials you reviewed, did you see whether ZHP tested, at any time, to see if DMF could degrade and yield dimethylamine under the conditions used in the zinc chloride process?
MS. DAVIDSON: Objection.
THE WITNESS: So if I go to my report, I think the answer is there.
Number 169, it says, and

it's the third line, But as Mr. Dong explains, this was because both sodium azide and sodium nitrate had been used before the process changed, and ZHP concluded, through the risk assessment process, that the increased amount of these substances did not significantly increase the potential risk of sodium azide or sodium nitrate. Moreover, even though ZHP had concluded the potential risk was low, it still conducted testing to determine residual amounts of those substances and performed a further risk assessment based on that testing.
So they did look at what was going on.
BY MR. SLATER:
Q. I just asked you whether ZHP, to your knowledge, ever performed any tests to determine whether DMF could

degrade and give off dimethylamine under the conditions of the zinc chloride process.
Do you know whether they did or not? Did they perform any test on that?
MS. DAVIDSON: Objection.
THE WITNESS: I don't recall whether they did any tests or not.
However, the common practice of industry would have been to effectively look at known solvents. And this was a known solvent.
The risk assessment would have occurred -- the assessment that you are asking would have occurred during development phases and not during commercial manufacture.
The development phases were done at a different site and they were investigated and studied over the course of more than two years.

BY MR. SLATER:
Q. Can you answer my question, please?
A. I answered your question, which was, did they look at this test, did they test for this?
And my answer is still, ZHP looked at the new process, the zinc chloride process with DMF, over a period of longer than two years in the development workshop at a different site.
And they concluded that the process was not generating anything undesirable, so.
Q. Could you please answer my question?
MS. DAVIDSON: Objection.
THE WITNESS: I answered the question.
ZHP, over two years, investigated the raw materials and the process at their development site and reported that data.
BY MR. SLATER:

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Q. Can you answer my question, please?
MS. DAVIDSON: Objection. You're badgering the witness. He's answered your question to the best of his ability.
BY MR. SLATER:
Q. Please answer.
MS. DAVIDSON: Objection.
THE WITNESS: ZHP -- ZHP tested all the raw materials and the product from the process in their development facility over a period of greater -- longer than two years.
BY MR. SLATER:
Q. Did ZHP ever, to your knowledge, ever do a test to determine whether, under the conditions of the zinc chloride process, DMF could degrade and give off dimethylamine; yes or no?
Was that specific test ever done by ZHP, to your knowledge?
MS. DAVIDSON: Objection.

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Asked and answered.
THE WITNESS: I have answered the question twice or three times.
So did ZHP ever do it? As I've said, they did it in their development facility. In a commercial setting, it would be against the GMPs to begin to do tests on the site for whatever reason, whatever purpose.
BY MR. SLATER:
Q. Your testimony is that as part of the risk assessment, ZHP performed a specific test to determine whether DMF could degrade and give off dimethylamine under the conditions of the zinc chloride process?
It's your understanding they actually did that test as part of the risk assessment; do I understand you correctly?
MS. DAVIDSON: Objection. Asked and answered.

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Mischaracterizes testimony. Badgering the witness.
THE WITNESS: That's not what I said. What I said was, they -- raw materials that were being used in the process were reviewed, were assessed, were risk assessed, for ensuring that the process was safe.
MR. SLATER: Let's take that exhibit down. And let's go back to the deviation investigation report, please. Page 170.
MS. DAVIDSON: What exhibit number was that again? Could someone remind me?
MR. SLATER: I don't remember. It's either Exhibit-5 or 6. Why don't we find out. Exhibit-5.
Actually, let's start off -- yeah. Okay. That's good.
BY MR. SLATER:
Q. Looking at page --

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MR. SLATER: Actually, you know what, Chris, let's go back. Let's go to Page 9, actually. Sorry about that.
BY MR. SLATER:
Q. Okay. We're looking now at Page 9 of Exhibit-5, the deviation investigation report.
And I'd like to look starting in the middle of the page. And it says, For further confirmation, the following lab scale trials were designed and performed to verify the concluded formation mechanism of NDMA. The amount of NDMA formed by quenching under different temperatures is shown in the table below.
Have you seen this page and taken this into account in forming your opinions in this case?
A. Yes.
Q. So you were aware that, as part of their deviation investigation, ZHP actually did lab tests where they had

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DMF at the same temperature for the same time period as under the zinc chloride process and then, after that, combined the sodium nitrate and they proved that NDMA resulted; so you're aware of that, correct?

MS. DAVIDSON: Objection.

THE WITNESS: This document that you're looking at has some differences from the commercial scale batch.

If you are looking at Rows Number 1 and 2, it's actually saying the pH is adjusted to 1.

So the commercial process was not operating at pH of 1, number one.

Number two, this is a test where they are driving to make NDMA. They are not trying to make valsartan, they are trying to make NDMA in the valsartan process.

Point three, this document is after they have identified

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NDMA. This document, this deviation investigation, is actually trying to find the root cause of NDMA formation, and they're trying various process parameters to see what results would come from that. This is then reported to FDA.

BY MR. SLATER:

Q. All I asked you is if you knew this information when you wrote your report.

Is the answer yes or no?

MS. DAVIDSON: Objection.

THE WITNESS: Did I read the investigation report, yes.

BY MR. SLATER:

Q. And this showed that when DMF was heated to 135 degrees Celsius for 20 hours, it created dimethylamine, which then later combined with the sodium nitrate and NDMA was formed, correct? That's what this lab test shows, right?

A. This lab test shows that if

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DMF, at 135 degrees, okay, 20 hours, then add MTB, water, sodium nitrate and adjust to 1 and then quench it as zero degrees and quench it at 10 and quench it at 20 degrees.

So it's different settings to generate or to create NDMA. That's what this document says.

I don't see any statement about dimethylamine.

Q. How would the NDMA have formed if the DMF didn't introduce the dimethylamine?

A. That is --

MS. DAVIDSON: Objection.

BY MR. SLATER:

Q. You're the -- you said you're a chemistry expert now, so tell me -- let me ask the question differently.

How did the NDMA -- rephrase.

You see the fourth column, it says, NDMA in parts per million? Do

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you see that?

A. Yes.

Q. How did that NDMA form?

MS. DAVIDSON: Objection. That's outside the scope of his opinions.

MR. SLATER: When you say that, so I know how to take the deposition, are you saying he's not giving chemistry opinions? Because he just said a few minutes ago he is. So I need to understand what's in and what's out.

MS. DAVIDSON: I didn't hear him say he's giving chemistry opinions. I think you're mischaracterizing his testimony now.

I will let the witness speak for himself.

THE WITNESS: I did not say that I was giving chemistry opinions. I said I do have a

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chemistry background.
My expertise in this is GMPs. And, again, to re-tread the point, I look at that screen and that tells me about the various conditions ZHP created to see what the -- you know, what levels of NDMA are formed.
BY MR. SLATER:
Q. Do you have any understanding as to how that NDMA formed in those lab tests, which you read about before you authored your report?
MS. DAVIDSON: Objection.
BY MR. SLATER:
Q. It's a yes or no. Either you know or you don't.
MS. DAVIDSON: Objection. I apologize for objecting in the middle of your questions. I always think they're done and then there's a postscript.
THE WITNESS: My role, my remit, was to look at the

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plaintiff experts and assess GMP -- GMP statements.
I was not here, on this project, to assess the chemistry. For that, there was Professor Xue.
What I'm looking at and what you asked me about this is whether, you know, dimethylamine is formed. And I'm saying, I don't see it on the screen.
BY MR. SLATER:
Q. Do you doubt the results of these tests for any reason as they're documented in this report from ZHP?
A. I have no evidence to doubt these results. And these were the results which were also submitted to FDA.
So, no, I don't doubt the results.
Q. Let's go to Page 170 of that document, please.
Looking now at the middle of the page, ZHP states in this report,

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According to the deviation investigation report, DCE18001, in tetrazole formation of crude step, DMF is used as solvent and zinc chloride is used as catalyst. Since the temperature might reach 135, plus or minus 5 degrees Celsius, and the reaction time period last for 20, plus or minus one hour, dimethylamine might be formed by decomposition of DMF.
Do you see what I just read?
A. Yes.
Q. Do you disagree with that conclusion that was drawn by ZHP in its deviation investigation report that I just read to you?
A. This is not a conclusion, because it's saying it's a probable root cause. It's using the word -- the language, which says, and the reaction, it might be formed. That's not an, it is formed.
This, as a deviation report, if submitted, which says it might be formed, my response would be, tell me

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whether it is or it isn't.
And, again, this document is with hindsight. This document is being used to assess and to find the different pathways.
Now, it also says, if the temperature -- it says, the temperature might reach 135, plus or minus 5 degrees. That information would be available in the batch report.
Q. Did you evaluate that issue at all, what temperatures were reached and what impact that could have on the DMF?
A. Again, my remit here was not chemistry.
Q. As a GMP expert, one of your rolls -- one of the things -- rephrase.
As a GMP expert, one of the things you needed to consider was what tests were performed by ZHP to determine whether they performed tests that were required by cGMP; that was within the scope of what you were doing, right?

MS. DAVIDSON: Objection.
THE WITNESS: So the tests which are required to be performed for release of material are defined as per USP. So those are the tests which are there.
BY MR. SLATER:
Q. Looking at the paragraph that I was just reading in, it continues, In subsequent step, when using sodium nitrite to quench redundant azide, valsartan was not separated.
Do you understand what that sentence means?
MS. DAVIDSON: Objection.
THE WITNESS: So the valsartan was not separated, as it didn't settle out.
BY MR. SLATER:
Q. The next sentence says -- rephrase.
Looking at the paragraph in the middle of the page, after the first couple of sentences about the formation

of dimethylamine, it states, In subsequent step when using sodium nitrite to quench redundant azide, valsartan was not separated. Thus, trace amount of NDMA is formed by reaction between dimethylamine and nitrous acid. To verify this conclusion, Huahai conducted simulation tests in the laboratory to demonstrate the DMF degradation and the generation of NDMA, the detail is in Table 4-40 as follows.
Do you see what I just read?
A. I see what you just read.
Q. Did you read that when you wrote your report? Had you read that information I just read to you?
A. I have read this before I wrote my report, yes.
Q. Did you factor that into the opinions you offered on GMP in this case; yes or no?
MS. DAVIDSON: I really -- I guess if you're asking simply about GMP, that's fine. I really

think you're delving into chemistry at this point, which are questions that are more appropriately asked to Professor Xue, who you already deposed.
But if you're just asking about his GMP opinions, that's fine.
THE WITNESS: So can you ask your question, please?
BY MR. SLATER:
Q. When you formed your opinions in this case regarding cGMP, did you take this information into account that I just read to you?
I just want to know if you took it into account when you formed your opinions; yes or no?
MS. DAVIDSON: Objection.
BY MR. SLATER:
Q. And, by the way, Doctor, I'm not asking for what the analysis was. I'm just asking if you took it into account.

MS. DAVIDSON: I really think we need to have one question pending, one question answered, because you just said six different things.
BY MR. SLATER:
Q. You can answer.
A. The challenge that I have answering your complex and multiple questions is you say, did I take this into account when making my GMP decisions?
This is an investigation, which is happening in a lab, in a lab setting, as a result of a deviation which has taken place before these activities were taking place, before these -- this data was being generated.
The reason the data was generated was to actually push the process to certain limits and see what the impact is. This is not happening in a GMP setting, even though it's a deviation investigation for a GMP

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deviation.
These are happening in a development setting to try and address, to try and understand how NDMA is formed.
So when you ask me straight questions expecting a yes-or-no answer, I struggle.
Q. When you formed your opinions regarding whether or not ZHP complied with cGMPs, was this information that I just read to you something that you factored into your opinion?
Either it's yes or no or you can say something like, it was irrelevant, I didn't have to consider it.
I don't know what your answer is, but I'd just like to know if it was something that you relied on, in part, in forming your opinions.
MS. DAVIDSON: I'm going to object. Asked and answered.
THE WITNESS: I have answered this question.
And when I'm reading this,

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this is about an event which is after GMP manufacturing has stopped. ZHP stopped manufacture of valsartan in June. This is happening sometime later, much later; and they're looking at it.
This is not what was happening in their GMP area. So for me to look at this and look at this data and to draw a conclusion based on what was going on beforehand would actually not be correct.
BY MR. SLATER:
Q. You see in the Table 4-40 it documents that, under these conditions DMA was a degradation product of the DMF under these conditions, correct? That's what's documented on the table, correct?
A. I see what the table says.
Q. If ZHP had wanted to, they could have run the same or similar lab tests as part of their risk assessment before they started manufacturing with

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the zinc chloride process, right?
A. This is happening with hindsight, with effectively looking at -- it's looking at what is happening in back end of 2018 and not what was happening early on.
Early on, when they were developing the process, ZHP had no reason to vary the process parameters, as per what's on the screen, and look for formation of NDMA. Point one.
Point two, as testified -- or as stated by FDA, neither industry nor the regulators knew about the chemical pathways that would form NDMAs.
Point three, again, as is stated by FDA, neither industry nor regulators had the methods to detect NDMA. Dr. Gottlieb specifically says, NDMA is difficult to detect and to isolate.
So I look at this and this is all after the event. This is with hindsight. ZHP would not have known.

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And, again, if ZHP -- the fact that ZHP did not know about the formation of NDMAs is, again, stated by the regulator. The regulators didn't know that these processes would result in NDMA.
MR. SLATER: We can take that document down now and go to a different document.
Is it 8 now, right? Did you put it up? You were waiting for me and I was waiting for you.
MS. DAVIDSON: So we're marking this as Exhibit-8?
MR. SLATER: We are.
- - -
(Whereupon, Exhibit Afnan-8, No Bates, 4/1/15 General Notices and Requirements, was marked for identification.)
- - -
MR. SLATER: Can you reduce it just so the whole document is on the page? Yeah. Perfect.

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BY MR. SLATER:
Q. So what we have on the screen as Exhibit-8 is an April 1, 2015, bulletin from the United States Pharmacopeia convention titled, General Notices and Requirements.
Do you see that?
A. Yes.
Q. Do you know what USP is?
A. Yes.
Q. What is USP?
A. USP is a not-for-profit independent organization that effectively writes two types of monographs. One is a general chapter, which is binding. And the other, which are not binding. So they write the specifications.
Q. When you say "they write the specifications," what specifications?
A. APIs, drug products, some raw materials.
Q. Let's go to Page 4, please.
And I'm looking now under Section 5.60, titled, Impurities and

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Foreign Substances.
Do you see that?
A. Yes.
Q. This says, Tests for the presence of impurities and foreign substances are provided to limit such substances to amounts that are unobjectionable under conditions in which the article is customarily employed.
Do you see what I just read?
A. Yes.
Q. Next this states, Non-monograph tests and acceptance criteria suitable for detecting and controlling impurities that may result from a change in the processing methods or that may be introduced from external sources should be employed in addition to the tests provided in the individual monograph where the presence of the impurity is inconsistent with applicable good manufacturing practices or good pharmaceutical practices.
Do you see what I just read?

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A. Yes.
Q. Did you know what I just read before I just read it to you?
MS. DAVIDSON: Objection.
MR. SLATER: I'm sorry, what's the objection?
MS. DAVIDSON: Does he know what you read before you read it to him? I don't even understand that question.
BY MR. SLATER:
Q. Doctor, the information I just read to you from this official USP document, were you aware of that before I read it to you, or is this the first time you're seeing that?
A. I was aware of that.
Q. When they refer to a change in the processing methods, here, with the TEA and sodium nitrite quenching process and the zinc chloride process, ZHP changed the processing methods for valsartan, correct?
A. Yes.

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Q. When they refer to impurities that may be introduced from external sources, one way that impurity can be introduced from an external source would be, for example, with the DMF in the zinc chloride process if the DMF, as purchased, contained dimethylamine as an impurity, correct?
A. It could, yes.
Q. And this is saying that in those circumstances, non-monograph tests and acceptance criteria should be employed in addition to the tests provided in the individual monograph where the presence of the impurity is inconsistent with applicable good manufacturing practices or good pharmaceutical practices.
That's what it states, correct?
A. That's what it states.
Q. The presence of NDMA and NDEA in the valsartan manufactured by ZHP was unwanted, correct?

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A. Correct.
Q. In fact, when it was discovered that the NDMA and NDEA were in the valsartan, that resulted in a recall of the finished-dose pills that had been manufactured with that API, correct?
A. So the text you have read to me relates to impurities and not unknown impurities.
The problem with NDMA, as stated by FDA, is that it's difficult to detect. The methods for its detection were not there. And that it was an unknown below a .1 percent, where ICH says you can have that impurity.
The method which is used for effectively looking at the residual solvents, as is stipulated by the USP, is GC FID, that doesn't detect the NDMA.
So if you know what you're looking for, then it is easy to go and look for it. But if one doesn't know what it's looking for, then it's very difficult to look for an unknown impurity

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that you're not aware of.
Q. The point of this section is instructing manufacturers that under certain circumstances, which we just went through, change in the processing methods or impurities that may be introduced from external sources, the manufacturer will need to develop and utilize non-monograph tests and acceptance criteria in order to address those circumstances; that's what this is saying, correct?
MS. DAVIDSON: Objection.
THE WITNESS: USP has no authority to -- to dictate to anyone what you have just read to me.
BY MR. SLATER:
Q. That's what the words on the page say, correct?
A. Your statement was, this instruction. And my response is, USP cannot instruct industry what to do.
However, industry followed Q3A, FDA adheres to Q3A, or follows that,

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and ZHP followed Q3A.
Q. The words on the page indicate that a manufacturer -- the word used is "should," should employ non-monograph tests and acceptance criteria where there's a change in the processing methods or impurities may be introduced from external sources.
That's what the words on the page say, that you're not limited just to the tests and acceptance criteria listed in the monograph; that's what the words on the page say, correct?
MS. DAVIDSON: Objection.
THE WITNESS: So, again, I'll repeat.
USP has no authority to say what -- to say to a manufacturer that you should do this. The same way that I have no authority when I say, Mr. Slater, please do not ask yes-or-no questions, okay.
BY MR. SLATER:
Q. Did I read the language

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correctly?
A. No, no, you didn't read the language incorrectly.
What I'm saying is that it says should. That's advisory. That's not binding. That's -- USP has no authority to tell manufacturers what to do.
Q3A is far more specific about what should be followed and should not be followed.
Q. A manufacturer, such as ZHP, would be expected, at least as of April 1, 2015, to understand that it would need to consider utilizing non-monograph tests and acceptance criteria as opposed to being limited by the USP tests and acceptance criteria in the monograph; that you'll agree to, that's what this provided -- that's what this information instructed or advised -- I'll start over, actually. Because I don't want to fall into the same back-and-forth with you.
You would agree with me that

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current good manufacturing practices, at least as of April 1, 2015, required the use of non-monograph tests and acceptance criteria suitable for detecting and controlling impurities that may result from a change in the processing methods or that may be introduced from external sources? That is something that manufacturers would have needed to understand, right?

A. As of January 2015, which is the date of this document, this document does not have any authority to stipulate to manufacturers that they need to use compendial or non-compendial tests, one.

Two, this is referring to known impurities.

Three, unknown impurities, unknown impurities, which by nature, by their name, are unknown, which are not expected to have an adverse -- to be -- to be carcinogenic, if one does not know of the presence of such impurities and the impurity is below .1 percent, as per

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ICH 3A, one need not look for that.

Q. Where does it say unknown impurities there? Where do you see unknown?

A. My point is --

MS. DAVIDSON: Objection.

Hold on, Dr. Afnan.

I know I didn't object for, like, three questions, you got out of practice.

BY MR. SLATER:

Q. Where does the word "unknown" describe the impurities?

A. It says, Non-monograph tests and acceptance criteria suitable for detecting and controlling impurities.

If an impurity is unknown and below .1 percent concentration and not anticipated to be in a cohort of concern, then there is no requirement, as per Q3, to look for it, to isolate it, to identify it, and then to come up with non-compendial methods to detect it.

Q. How would you identify NDMA

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in ZHP's valsartan without doing a test?

MS. DAVIDSON: Objection.

THE WITNESS: As per FDA and USP, USP's monograph for valsartan requires the use of GC FID. It required the use of GC FID then. It requires use of GC FID today, in 2023.

FDA also stated, acknowledged, that neither industry nor regulators had the test methods suitable for detecting NDMA in valsartan. And for that reason, FDA developed those methods and published those methods.

BY MR. SLATER:

Q. How would one have identified NDMA in valsartan without doing a test to confirm that there was NDMA in valsartan?

A. I've answered that question, and I'll answer again.

The methods, which were

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current up through June of 2018, in industry did not actually indicate presence of NDMA. As Dr. Gottlieb stated, it's a very difficult substance to detect. It's -- the methods are not there and -- the methods are not there and, also, they -- the substance is difficult to detect. It's a residual solvent, so it needs to be taken out of solution into a gas and then tested.

Q. Is there any other way to confirm whether or not there's NDMA in valsartan without running a test?

It's a yes-or-no question. I just want to know, can you do it without using a test?

MS. DAVIDSON: Objection.

THE WITNESS: If a firm anticipated, and I'll use the word firm, FDA, if it's anticipated that had the NDMA would occur, then they would look for it.

But, again, if I go to the FDA's 30th of August 2019

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statement, it says, Because it was not anticipated that NDMA would occur at these levels in the manufacture of the valsartan API, manufacturers would not have been testing for it. They would not have records that helped identify the issue during the -- during an inspection.

So this particular risk would not have been identified on an inspection. FDA agrees that NDMA was not anticipated.

BY MR. SLATER:

Q. It's your opinion that as a matter of cGMP, ZHP did not have to run any tests to determine if there was NDMA or NDEA in its valsartan unless and until it anticipated that there would be NDMA or NDEA present in the valsartan?

MS. DAVIDSON: Objection.

THE WITNESS: Can you read the question again? Or can you repeat the question? One or the

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other.

BY MR. SLATER:

Q. Is it your opinion that ZHP did not have to test for NDMA or NDEA in its valsartan until it actually anticipated that there was NDMA or NDEA present in the valsartan?

A. So as per ICH guidances, if presence of NDMA, or any other mutagenic substance, is not anticipated, then there is no test to be done for it.

Q. That's your understanding of ICH?

A. Yes.

Q. If ZHP had determined, based on an analysis of the potential chemical reactions and the potential presence of secondary amines and nitrous acid in its valsartan manufacturing processes, under those circumstances, would GMP have required ZHP to then run a test to see if there actually was NDMA or NDEA in the valsartan?

MS. DAVIDSON: Objection.

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THE WITNESS: So can you please repeat? I apologize, sincerely apologize to you, but can you repeat the question, please?

MS. DAVIDSON: It was a long question. You don't have to apologize.

BY MR. SLATER:

Q. If ZHP had actually identified the potential formation of NDMA or NDEA in its valsartan manufacturing processes and knew that that was a possible impurity that could be created by those processes, under those circumstances, would GMP have required ZHP to run tests to see if there was NDMA or NDEA in the valsartan?

A. Yes. But that's not the case here.

Q. We know from the documents I showed you before that ZHP should have anticipated at least the potential presence of dimethylamine in the zinc

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chloride process, because we know that that's a known impurity of commercial DMF; we've established that, right?

MS. DAVIDSON: Objection.

THE WITNESS: No, we have not. I did not agree to that.

BY MR. SLATER:

Q. You disagree or do you have no opinion?

Tell me what your opinion is on that.

MS. DAVIDSON: Objection.

BY MR. SLATER:

Q. Let me ask the question clearly.

A. Okay.

Q. Are you saying that you disagree that ZHP should have been on notice of the potential for dimethylamine to be an impurity of the DMF it was purchasing? Are you saying they didn't have to be aware of that as a possibility?

MS. DAVIDSON: Objection.

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That was a compound question again. When you say "are you saying," I think you're characterizing testimony, in which case it was mischaracterized.

I really think this would go more smoothly if you stuck to one question at a time.

MR. SLATER: We're dealing with a country lawyer who is struggling through it. I'm doing the best I can.

MS. DAVIDSON: From the country of New Jersey?

All right. Dr. Afnan, I'm sorry for the side show. Do you understand the question you're being asked right now or do you need one question repeated to you?

THE WITNESS: It's a very --

BY MR. SLATER:

Q. You're obviously struggling with it.

Let me do the best I can,

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because I obviously am struggling here, too. Because I can't get an answer, so it's obvious that my questions are no good.

Do you have an opinion, one way or the other, as to whether or not ZHP should have been aware of the potential for dimethylamine to be an impurity of the DMF it was using in the zinc chloride process? I just want to know right now if you have an opinion on that.

A. ZHP was not aware --

Q. Do you have an opinion on the question --

MS. DAVIDSON: Whoa. No. He was in the middle of a sentence, Adam. Come on.

MR. SLATER: So you're encouraging your witness not to answer with a direct answer? Okay. Thank you.

MS. DAVIDSON: What do you mean? He was in the middle of an

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answer, and you stopped him and interrupted him. I don't know what his answer was going to be.

MR. SLATER: Counsel, all I asked was if he has an opinion on that. I didn't ask what it was.

MS. DAVIDSON: I understand.

MR. SLATER: So I'm entitled to the answer to the question.

MS. DAVIDSON: That does not entitle you to interrupt someone mid question -- mid answer, Adam, you know that.

And you wouldn't put up with that if I were to do the same.

MR. SLATER: Please stop talking. I'm just saying, you've talked a lot and it's taking a lot of time.

BY MR. SLATER:

Q. Just answer the question, Doctor.

MS. DAVIDSON: What question is pending? Because I don't know.

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MR. SLATER: I'm sorry you lost track, but you're not the person I'm deposing.

BY MR. SLATER:

Q. So please answer the question.

MS. DAVIDSON: I'm asking the court reporter to repeat the question so we know what the question is.

MR. SLATER: We're not going to have the court reporter repeat the question.

BY MR. SLATER:

Q. Doctor, do you, yes or no, have an opinion, I just want to know if you have an opinion, I don't want to know what it is, as to whether or not ZHP should have been aware of the potential for dimethylamine to be an impurity of the DMF it was using in the zinc chloride process; yes or no? Do you have an opinion?

MS. DAVIDSON: Objection.

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Objection. To all three questions that were just combined into one.
THE WITNESS: I can't answer that. I genuinely cannot answer that.
MS. DAVIDSON: We've been going a little more than an hour. So, Adam, when you're at a stopping point --
MR. SLATER: I'm not there yet.
MS. DAVIDSON: What do you mean?
MR. SLATER: I'm not at a stopping point right now.
MS. DAVIDSON: Do you have one or two questions on the same topic --
MR. SLATER: I'm not going to be -- look, you can walk out of the deposition and take a break whenever you want. But I'm in the middle of a line of questioning. There's no rule in the world that

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says every hour we take a long break. I want to finish this line of questioning.
I'm not agreeing to a break right now.
MS. DAVIDSON: First of all --
MR. SLATER: You know what, I don't want to talk to you, honestly, about this. I'm not ready to break. I'm in the middle of a line of questions, so it's not a good stopping time.
I will now continue, unless you stop the deposition and walk out with your witness, and then I'll have to wait for you to come back.
MS. DAVIDSON: So two things. Dr. Afnan, do you need a break or do you want to go a few more minutes?
MR. SLATER: I'm in the middle -- there's a question that

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I'm in the middle of asking. You're now trying to stop me from continuing. I don't think that's kosher.
Can I please finish this line of questioning? You're wasting my time. And I don't appreciate it.
MS. DAVIDSON: Dr. Afnan --
BY MR. SLATER:
Q. Doctor, do you know whether or not ZHP knew that dimethylamine was a potential impurity of the DMF it was using in the zinc chloride process? Do you know whether they knew about that or not?
MS. DAVIDSON: Objection.
THE WITNESS: I do not recall, and I would need to look at the documentation to say yeah or nay.
And I would like a break.
BY MR. SLATER:
Q. If ZHP knew --

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MS. DAVIDSON: Whoa. He just said he wants a break, so let's take the break and follow up afterwards.
MR. SLATER: Off the record at defense counsel's insistence.
VIDEO TECHNICIAN: We're off the record at 1:55 p.m.
- - -
(Whereupon, a brief recess was taken.)
- - -
VIDEO TECHNICIAN: We're back on the record at 2:07 p.m.
BY MR. SLATER:
Q. To be very clear, Dr. Afnan, are you relying on Dr. Xue in order to form any of your opinions?
Is there anything that Dr. Xue has opined on where you would say, I'm relying on that opinion in order to form this other opinion?
MS. DAVIDSON: Objection.
THE WITNESS: So if I go to

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Statement Number 190 of my report, okay, it's regarding the July 2017 e-mail, which the word "rely" is -- I refer to his statement.

But, again, I have verified it by studying the -- Ms. Jucai Ge's testimony on the subject.

BY MR. SLATER:

Q. So this is where you referred to as detailed in the report of Fengtian Xue, an expert chemist with native fluency in Chinese, plaintiffs' experts misread this highly technical e-mail?

A. Yes.

Q. And am I understanding correctly that one of the reasons you're relying on Dr. Xue is because it's your understanding that he is fluent in Chinese?

MS. DAVIDSON: Objection.

THE WITNESS: As I said, I verified by reading Jucai Ge's testimony where she is questioned

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extensively about the e-mail.

BY MR. SLATER:

Q. So you're not relying on Dr. Xue at all?

A. As I said --

MS. DAVIDSON: Objection. Hold on Dr. Afnan.

THE WITNESS: For me to form an opinion, okay, for me to form an opinion on the subject, I've looked at that e-mail, I've looked at Jucai Ge's statement, I've looked at -- sorry, deposition. I have looked at all of those. And I have also considered this.

If you ask me which is the document that I am putting the most weight on, that's Jucai Ge's testimony -- or not testimony, deposition.

BY MR. SLATER:

Q. I notice that you spoke to Jucai Ge Ge, according to your report.

Did I read that correctly?

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A. Yes.

Q. What day was that?

A. I don't remember. Maybe November, maybe December. It was before my report.

Q. How many times did you speak to her?

A. Once.

Q. How long did you speak to her for?

A. I do not remember.

Q. Did you record the conversation?

A. No.

Q. Did you take notes of the conversation?

A. No.

Q. Do you remember what she told you?

A. I remember what I asked and what she told me.

Q. What was that?

A. I asked about customer complaints or customer questions about

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unknown peaks.

Q. When you say you gave the most weight to Jucai Ge's deposition, what in particular about her deposition did you put weight on with regard to your understanding of the July 27, 2017, e-mail?

A. As she said in her deposition of April 2022, she had actually done -- you know, she said, I prepared for the deposition, I went back and read the e-mail, I studied the e-mail. So she had actually done background search regarding the e-mail.

Q. You said you read the e-mail.

Did you read the e-mail in English or in Chinese?

A. English.

Q. Which version?

A. The version that was in the plaintiff experts' references as exhibits to plaintiff experts.

Q. Did you read the testimony

of Dr. Min Lee where he testified, on behalf of ZHP, has to what the e-mail said?

A. I do recall some of the depositions of Dr. Lee.

Q. Was Dr. Lee's reading of the e-mail of any significance to you in forming your opinions about that e-mail?

MS. DAVIDSON: Objection.

THE WITNESS: So Dr. Lee's deposition was -- his statements were not as detailed or as informed as Jucai Ge Ge's.

BY MR. SLATER:

Q. Did you read John Du's deposition and his testimony as to what the e-mail said?

A. I read that some time back.

Q. Was John Du's testimony as to what the e-mail said of significance to you in forming your opinions about the e-mail?

MS. DAVIDSON: Objection.

THE WITNESS: I read a lot

of material to form an opinion about the e-mail and to then make a statement.

BY MR. SLATER:

Q. Was John Du's testimony in regard to what the e-mail said significant to you in forming your opinion about the e-mail?

MS. DAVIDSON: Objection.

THE WITNESS: Would it be possible for you to tell me what you mean by "significance"?

BY MR. SLATER:

Q. Something that you would say that's part of the reason why I formed my opinion is because based on what John Du said; I'm relying on what John Du said as part of the basis for my opinion.

A. So based on that, I'll give the answer that I've already given.

I looked at a lot of depositions and materials regarding the e-mail before I concluded my statement which is in my report.

Q. I understand you looked at a lot of materials.

I'm asking if your reading of John Du's testimony, as to what the e-mail said, was significant to you in forming your opinion?

MS. DAVIDSON: Objection.

THE WITNESS: I read a lot of materials, including John Du's, to then come to a conclusion.

BY MR. SLATER:

Q. Did you read the translation of the e-mail that was provided by ZHP to us in the litigation?

A. I read the translation that was submitted as evidence of the plaintiff experts.

Q. You don't know what the e-mail said yourself, you have to rely on other people to tell you what it said, right?

MS. DAVIDSON: Objection.

BY MR. SLATER:

Q. You can't read the e-mail in

Chinese -- new question.

Since you can't read the e-mail, as it was written in Chinese, you have to rely on the accuracy of translations by other people and the testimony of other people as to what it said, correct?

MS. DAVIDSON: Objection.

THE WITNESS: So I don't speak Chinese. I read it in English. I read the testimony -- the deposition, not testimony, the deposition of Jucai Ge, which is quite detailed, and she provides far more information than anybody else about the e-mail.

I also looked at what Dr. Xue says in his testimony, which I have then referenced in my statement.

BY MR. SLATER:

Q. Since you can't read the e-mail yourself, as it was written in Chinese, you have to rely on other people

to tell you what it said, correct?
MS. DAVIDSON: Objection.
THE WITNESS: So there is a translation. I read the translation and I looked at that translation in English.
There is nobody pointing me and saying, you know what, as you read this, it means this, that or the other. And that's why I was most interested in Jucai Ge's deposition, because that's quite detailed.
BY MR. SLATER:
Q. Doctor, I'm honestly not sure why it is that this question is creating so much difficulty. It's literally a foundational question to move forward.
You have to rely on the translation of the e-mail and the testimony of other people to understand what the e-mail said, it's not something you can read firsthand as written,

because you don't read Chinese, correct?
MS. DAVIDSON: Objection.
THE WITNESS: I do not read Chinese. And, again, as Jucai Ge says, the e-mail is confusing, it badly written, and she is reading it in Chinese.
So, no, I'm not reading Chinese. I'm reading the translation that was provided in the plaintiff experts -- by the plaintiff experts.
BY MR. SLATER:
Q. Your only basis to say the e-mail is confusing and badly written is Jucai Ge saying that in testimony, right? You have to rely on her for that, right?
A. She says that, Dr. Xue says that. Jucai Ge talked to Dr. Lin, who was the author, and the author says, no, that's not what I said.
Q. If I understand correctly, your understanding of what the e-mail says really comes from Jucai Ge's

deposition and Dr. Xue's report; that's the basis for your understanding of what it says, correct?
A. And the text of the translated text, as well as the attachment that it refers to.
Q. I want to understand if you have a certain understanding of the e-mail, okay?
So I'm just asking, do you understand it to say a certain thing? That's all my question is. I'm not asking for a speech. I'm not asking about anybody else on earth.
I know that you're smiling and you're laughing, but I'm not asking about anything else. So please don't tell me about anything else so we can actually use my time efficiently, because I want to finish your deposition today.
So please show me that respect that you'll just answer my question.
MS. DAVIDSON: I'm going to

object to that colloquy. I'm objecting to that colloquy. You're badgering.
MR. SLATER: You can object. I'm going to continue.
MS. DAVIDSON: You're interrupting me. Please do not badger the witness. Please do not speak to the witness that way. You're asking the witness to show you respect, so show respect to the witness.
Thank you.
MR. SLATER: Thank you very much for those instructions. I appreciate it.
BY MR. SLATER:
Q. Does your -- rephrase.
Do you understand the e-mail to say, in part, that there is NDMA in valsartan; yes or no?
A. The e-mail, based on the translation that I have seen, as well as the patent which was accompanied with it,

alone without anything else, does not tell me there is NDMA in valsartan.
I have supporting evidence from Jucai Ge and Dr. Xue, and others, that effectively says that's not the statement that the e-mail is making.
Q. Who are the others?
A. There are others who have been deposed.
Q. Who else said that it doesn't say that there's NDMA in valsartan?
A. The two -- the two others that I cannot recall right now that you mentioned.
Q. You think that Min Lee and John Du said that the e-mail does not indicate that there's NDMA in valsartan? You think that's their testimony under oath?
MS. DAVIDSON: Objection.
THE WITNESS: Yes.
BY MR. SLATER:
Q. Is it your understanding

that the e-mail indicates that the NDMA in the valsartan was caused by the quenching with sodium nitrite?
MS. DAVIDSON: Objection.
THE WITNESS: The e-mail is talking about Impurity K, it's not talking about NDMA. It's taking about irbesartan process. And it's talking about, specifically, formation of a nitroso compound which looks like a nitroso valsartan. There is a chemical formula given in that e-mail which is different from that of valsartan.
BY MR. SLATER:
Q. Are you aware of the language where it says that the NDMA is produced by the quenching of the valsartan with sodium nitrite? Are you aware that the e-mail says that, or do you dispute that the e-mail says that?
MS. DAVIDSON: Objection. Are you referring to a specific

translation of the e-mail? Are you referring to the e-mail?
MR. SLATER: I'm referring to the e-mail.
MS. DAVIDSON: The e-mail in Chinese?
MR. SLATER: Counsel, I'm not going to go back-and-forth with you. Just -- you objected to the form of the question. Please answer.
I'm done with these discussions with you. I have three more hours on the record. I'm not going to spend it talking to you.
BY MR. SLATER:
Q. Please answer the question, Doctor.
A. Can I please get the e-mail on the screen?
Q. Sure. One second.
A. Thank you.
Q. I'm going to get you the

e-mail, Doctor.
A. Thank you.
And if -- Mr. Slater, if I smile, I am not disrespecting you.
Q. I don't mind smiling. Smiling is great. It's a healthy thing to do. It's good for endorphins.
MR. SLATER: I think we're up to Exhibit-9 now, right?
- - -
(Whereupon, Exhibit Afnan-9, ZHP00190573-0574, Notice on the Results of the Report of the Preliminary Investigation on the Formation of Unknown Impurities Resulting from the Sodium Azide Quenching in Crude Irbesartan, was marked for identification.)
- - -
BY MR. SLATER:
Q. So on the screen is Exhibit-9.
A. Yes.
Q. That's the e-mail

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translation that you saw?
A. That is the e-mail translation that I saw.
Q. Let's go to the second page, please.
Do you see at the very top of the second page of the e-mail there's some language up above some chemistry formulas? Do you see that?
A. Yes.
Q. And they're talking in the first sentence about something that they saw in irbesartan that they're working on a manufacturing process for, they're experimenting with a manufacturing process, and they're talking about irbesartan, right?
A. Yes.
Q. And it says, Through the secondary mass spectrometry analysis, it can be inferred that the extra NO substituent is in the cyclic compound fragment and it is very likely that it is an N-NO compound.

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I'm going to stop there.
They're talking about what they're seeing in the irbesartan, right?
MS. DAVIDSON: Objection.
THE WITNESS: Can I go to Page 1 of this e-mail, please?
BY MR. SLATER:
Q. Sure. Do you need us to do that for you?
MR. SLATER: Go ahead. We'll put on Page 1, let's go.
THE WITNESS: I have it open.
According to the results of our telephone conversation with the technology department of Chuannan Plant 1 today, due to the incomplete quenching of sodium azide caused by the separate treatment of irbesartan sodium azide wastewater, there is a frequent occurrence of muffled explosion in the production process. So the technology

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department carried out the technical improvement by which the sodium azide quenching takes place in the unstratified step in the crude irbesartan process.
However, after the improvement, there is an unknown impurity of about .544 percent at 26 minutes in the crude irbesartan, and it is the largest impurity in the irbesartan crude product. We investigated, at 26 minutes, unknown impurity that occurred in the crude irbesartan after the improvement -- thank you -- of the sodium azide quenching process sent by the technology department.
Based on the results of these two days, currently it can be confirmed that the impurity is a nitroso derivative of irbesartan and its precise molecular weight of 458.2306, and the signal peak

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of M plus K plus 496.1865 can also be observed. The matching molecular formula is C25H27N702. Compared with the molecular formula of irbesartan, it has an extra NO but missing one hydrogen atom. The estimated possible structural formula is shown as follows.
Okay. Now, he attached to this e-mail, in Chinese, the patent. And the patent talks about Impurity K, Impurity K being present in that process, not in -- not a nitrosamine in valsartan.
So I've gone through this e-mail several times. And, again, this is where Jucai Ge's testimony or -- deposition, not testimony, becomes very helpful.
BY MR. SLATER:
Q. Great. All I asked you is if that first part of the sentence at the top was referring to irbesartan up to the

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semi-colon.
Do you agree that's talking about what they saw in the irbesartan?
MS. DAVIDSON: Objection.
THE WITNESS: So I would have to guess. I -- my assumption is that the whole e-mail is about irbesartan, from beginning to the end.
BY MR. SLATER:
Q. The first sentence at the top of Page 2 says, Through the secondary mass spectometry analysis, it can be inferred that the extra NO substituent is in the cyclic compound fragment and it is very likely that it is an N-NO compound.
Do you see what I just read?
A. Yes.
Q. And you just confirmed your understanding is that has to do with what they were seeing in irbesartan, right?
MS. DAVIDSON: Objection.
THE WITNESS: I did not.
BY MR. SLATER:

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Q. You literally just said the entire e-mail is about irbesartan.
Wouldn't that sentence be included?
A. Well, that is -- again, we go back to, you know what, it's the translation of the e-mail, so on and so forth.
Potentially, yes, it's referring to irbesartan. Okay.
Q. Now, after the semi-colon Dr. Lin says, It is similar to the N-nitroso dimethylamine that occurs in valsartan when quenched with sodium nitrite.
Do you see what I just read?
A. Yes.
Q. Forgetting about the e-mail for a second, as a matter of fact in the world, as of July 2017, there was NDMA in valsartan and it was occurring when the valsartan was quenched with sodium nitrate. That's when the NDMA was forming.

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You know that for a fact, correct?
MS. DAVIDSON: Objection.
THE WITNESS: I do not. Again, going back to Jucai Ge, Dr. Lin was situated -- was physically placed at a different site, different location. He was looking -- he was a development department -- you know, technology department. He was looking at a manufacturing process for irbesartan.
And, actually, specifically looking at the effluent coming from the process and looking at what could be formed and what could not be formed.
So as he's doing this and he goes on to say that, you know, find the patent, which he had researched and, effectively, this is a hypothetical e-mail, because he's responding to the patent.

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And the patent talks about Impurity K, which is a nitroso valsartan compound.
BY MR. SLATER:
Q. I'm not asking about the e-mail right now, this question, okay.
Was there NDMA in the valsartan manufactured with the zinc chloride process?
A. That was discovered in June 2018.
Q. So the answer is yes, right?
A. In June 2018, ZHP identified NDMA in valsartan.
Q. The NDMA was formed at the point when the sodium azide was quenched with sodium nitrite; that's when the NDMA formed, correct?
A. According to FDA analysis, NDMA was present in the -- NDMA was present in their second process where sodium nitrite was formed. It was -- and then into the zinc chloride process. That was discovered in June 2018.

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Q. I'm sorry, Doctor, I have to ask again, because I have no idea what you just said. I just didn't understand it.

Doctor, the NDMA formed in the zinc chloride process was formed when the sodium azide was quenched with sodium nitrite; that's when the formation occurred, correct?

MS. DAVIDSON: Objection.

THE WITNESS: So as of yet, there is no statement by FDA which says it formed then. The investigation -- deviation investigation, which we were discussing earlier, specifically is looking at multiple pathways of formation of NDMA.

BY MR. SLATER:

Q. Do you have an opinion as to when the NDMA formed during the zinc chloride process? Was it during the quenching with sodium nitrite or during another part of the process, or do you

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have no opinion?

MS. DAVIDSON: Objection.

THE WITNESS: That I would have to defer to a synthetic organic chemist. I would suggest Dr. Xue.

BY MR. SLATER:

Q. I would like you to assume that this e-mail says that what they were seeing in the irbesartan was similar to the NDMA that occurs in valsartan when quenched with sodium nitrite. I'd like you to assume that that's what the e-mail says, okay?

Do you understand that I'm asking you to assume that?

A. So you want me to go into hypothetical, okay.

Q. I do. You may not know this, but we're allowed to ask hypothetical questions of expert witnesses.

A. I appreciate that.

Q. And I'd also like you to

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assume that there was NDMA in valsartan manufactured with the zinc chloride process and it occurred and formed when the sodium azide was quenched with sodium nitrite. I'd also like you to assume that, okay?

A. Okay.

Q. Would that change your opinion as to when ZHP was aware there was NDMA in its valsartan and how it formed in July of 2017?

MS. DAVIDSON: Objection.

THE WITNESS: You have two assumptions and then you would like me to assume a third, based on your two assumptions.

So, again, I would like to go back to what FDA says, what my testimony said, my report states is that neither the FDA nor industry knew how NDMA was formed, neither FDA nor industry had methods to test for them.

And so, therefore, if they

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didn't know how to test for it and if they didn't know it was there, then the question is that -- the engagement between you and I is purely theoretical, and not even theoretical, it's hypothetical.

So, you know, at the time of 2017, ZHP did not know that NDMA was present in its valsartan.

BY MR. SLATER:

Q. Can you answer my question, please?

MS. DAVIDSON: Objection.

THE WITNESS: Please ask it again.

Hypothetical 1 was what, that there is --

BY MR. SLATER:

Q. I'll ask the question differently for you.

A. Thank you.

Q. I already have your one answer, so we have that for the record in the transcript as your sworn testimony.

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Now I'll ask a different question in a different way.
If the e-mail says that there was NDMA in valsartan and it occurs when it's quenched with sodium nitrite, that would be an accurate statement, correct?
MS. DAVIDSON: Objection.
THE WITNESS: If the e-mail said NDMA was present, yes, but the e-mail does not say that.
BY MR. SLATER:
Q. And if that was a correct statement -- well, rephrase.
And if the e-mail says that there was NDMA in valsartan and it occurred when the valsartan was quenched with sodium nitrite, not only would that be a true statement, but it would also prove that at least some people in ZHP were aware of the presence of the NDMA and how it was forming, right?
MS. DAVIDSON: Objection.
THE WITNESS: ZHP did not

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know -- again, you know, ZHP did not know.
Dr. Lin says that's not what he said in the e-mail. Jucai Ge says that's not what it says in the e-mail. So, you know, it's purely hypothetical to go down this path that if this happened and that happened, then this other thing would have happened.
As your statements, your conclusion, based on your theoretical statements, are connected. But that's not the case here. I really need to make sure my testimony is accurate, as accurate as it can be.
BY MR. SLATER:
Q. If ZHP knew that there was NDMA in valsartan and knew that it was forming during the quenching of the valsartan during the manufacturing process with sodium nitrite, if they knew that, good manufacturing practices

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required them to immediately notify their customers and the FDA and cease manufacture with that process until they got further guidance, correct?
MS. DAVIDSON: Objection.
THE WITNESS: ZHP did exactly that in June 2018.
BY MR. SLATER:
Q. And if they knew that in July of 2017, they would have been required to do it in July of 2017 and not wait until June of 2018, right?
A. Whenever they would have become aware of it, they would have had to act. But that was not the case, they did not know in June 2017.
Q. Well, you actually don't know when they knew; you're just deciding which witnesses to believe and which translations of the document to believe, but you don't know at all what happened, right?
MS. DAVIDSON: Objection.
THE WITNESS: Respectfully,

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incorrect. I -- you know, seven years at FDA told me to look for evidence, look for evidence, look for evidence.
The evidence is there when they received an e-mail, or a communication, from Novartis saying, what is that peak which is there, send us data. They did send data. They sent GC FID data. They also sent GCMS data which was not alluding, you know, the unknown peak.
BY MR. SLATER:
Q. Did you -- I'm sorry, I didn't realize you were still talking. Go ahead.
A. So Novartis actually told them that the chances are that using your method, it will dilute at a different time than ours. FDA didn't know either.
So FDA, who had reviewed the ANDAs related to this API, would have known, would have actually assessed

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whether NDMA would have been formed or not.

So ZHP didn't know until June 2018.

Q. You just mentioned the FDA review of the ANDAs.

You just referred to that, right?

A. Yes.

Q. When the FDA did whatever review it did of the ANDAs that were filed, is it your testimony that the FDA would, at that point, have done a cGMP-compliant risk assessment of the entire manufacturing process?

MS. DAVIDSON: Objection.

THE WITNESS: So there are parallel activities for an approval process going on. One activity is what's going on at the API facility. And that API facility was also inspected in, I think, 2011 and then in 2016 by EDQM, who accepted the facility

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and gave them a GMP certificate.

FDA had the DMF, which -- which the process, there's a chlorine process had been filed through as an amendment. That was also there.

The ANDA process would have looked at, effectively, the tests for the API. It would have looked for the process of making the drug substance, and -- the process, as well as the release criteria for the raw substance. And they would have looked at whether the chemistry recorded in the sections of the Model 3 would be accurate, correct or not.

And that would have then been verified through either a GMP inspection or a PAI inspection.

BY MR. SLATER:

Q. Could you answer my question, please?

MS. DAVIDSON: Objection.

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BY MR. SLATER:

Q. Or I can ask it again.

Do you want me to ask you again, Doctor?

Because I don't really understand what you just said. So I'm going to try to ask a question that's specific and hope that I can get a specific answer. That's my hope.

When the FDA reviewed the ANDAs that were submitted with regard -- which then incorporated, by reference, the DMFs for the TEA with sodium nitrite quenching and the zinc chloride processes, did the FDA perform a cGMP-compliant risk assessment of each of those manufacturing processes?

A. I did respond.

Q. It's a yes-or-no question.

Can you just tell me if the review by the FDA is to the level of a cGMP-compliant risk assessment?

A. With all due respect, sir, your question is wrong.

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They review an ANDA application. It's not a GMP activity. It's managed through other sections of the CFR. So FDA would have looked at the sections of the common technical dossier that would have been provided. They would have also looked at the GMP status of the facility for approval of the ANDA.

Q. Looking at the e-mail of July 27, 2017, the second paragraph after the chemistry diagrams says, If it is confirmed as the above-speculated structure, then its toxicity will be very strong and there will be an extremely high GMP risk. This is a common problem in the production and synthesis of sartan APIs. It is recommended to improve other quenching processes (such as NACIO) along with the optimization of the valsartan sodium azide quenching process.

Do you see that?

A. I see that.

Q. So, first of all, where he says, This is a common problem with the

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production and synthesis of sartan APIs, you understand that ZHP manufactured other sartans, including irbesartan?
A. Yes.
Q. If ZHP was aware that the quenching with sodium nitrite causing nitrosamines was a common problem in the production and synthesis of sartan APIs, they would have been duty bound to notify the FDA and their customers with regard to all of their sartans, correct?
If that's what they knew, they would have been required to notify the FDA and their customers, right?
A. As the e-mail says, it says if it is confirmed. And by the way, that's NACLO, sodium hydrochloride.
So it says, If it is confirmed as the above speculated structure, then its toxicity will be strong. Okay.
Q. He then says, It is recommended to improve other quenching processes along with the optimization of

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the valsartan sodium azide quenching process.
If that's correct, that he was recommending, based on everything he talked about, optimizing the valsartan sodium azide quenching process, based on having stated above that the NDMA was formed during the sodium nitrite quenching of the sodium azide, that would be something that ZHP would have been required to notify the FDA and their customers of immediately, right?
A. If that was the case, they would have had to inform FDA and customers immediately. That was not the case.
If I may be allowed to read the next line of the next paragraph. I have also attached a patent of a 2013 sodium azide sodium hyperchloride quenching method by Zhejiang Second Pharma Company Limited. They proposed that the use of sodium azide quenching will result in the formation of N-NO

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impurities.
Which, actually, as per the attached, is a -- is a nitroso valsartan. You know, the nitroso compounds are many and plenty. And, therefore, that compound that he's referring to, if you look at the patent, is actually Impurity K.
Q. Do you see where this says, At the same time they -- meaning this other company, Zhejiang Second Pharma Company -- used ZHP's crude valsartan in their LC-MS test and detected this impurity.
And the impurity that was referred to above in the valsartan was NDMA, correct?
A. Hold on. I lost you. Okay. Allow me.
So, okay. What was your question, please?
Q. This states that this other pharmaceutical company used ZHP's crude valsartan in their LC-MS test and

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detected this impurity.
The impurity that was identified up above in the valsartan was listed as NDMA, correct?
A. Can you point me to where it says this is NDMA?
Q. Sure.
MR. SLATER: Scroll to the top, please.
THE WITNESS: Okay. This is similar, similar, to N-nitrosamines. This is similar.
BY MR. SLATER:
Q. You don't have to read the rest of the sentence, Doctor. With all due respect, it says that what they saw in the irbesartan was similar to the NDMA that occurs in valsartan when quenched with sodium nitrite.
That's what the document says, right?
MS. DAVIDSON: Objection. That's what the translation says.
THE WITNESS: Which, again,

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if I follow what I said earlier, if I look at both Professor Xue and if I look at Jucai Ge, who spoke to Dr. Lin in detail and asked the questions, Dr. Lin says, I never made that statement. That was not my intent.

So as we go through to the second question, or the last paragraph, yes, the statement which says, At the same time they used ZHP's crude valsartan.

So this e-mail was about Impurity K. This is about Impurity K, which is a nitroso valsartan. It's a valsartan molecule with an N-O attached to it.

BY MR. SLATER:

Q. Now you think the whole e-mail is about Impurity K? It's not about irbesartan anymore?

MS. DAVIDSON: Objection.

BY MR. SLATER:

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Q. I'm just asking.

Before you said the whole e-mail was about irbesartan, now it's about Impurity K?

MS. DAVIDSON: Wait a minute. That's really mischaracterizing his testimony and --

MR. SLATER: Without you giving him what to say. You objected. He can answer.

MS. DAVIDSON: I'm not telling --

MR. SLATER: He doesn't need to take signal from you. The last one he followed your objection and followed it and said exactly what you said. Let's try not to do that, please.

MS. DAVIDSON: That is literally the pot calling --

MR. SLATER: I don't want to argue with you. I really don't.

MS. DAVIDSON: I understand,

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Adam. But you're arguing with the witness. And my job today is to make sure that this deposition proceeds in an appropriate manner.

The way you're talking to the witness is rude. So I'm just asking you not to.

MR. SLATER: I don't think I'm being rude at all. There's an audiotape of this transcript -- of this deposition, the video has an audio. So anybody that needs to look at it, I stand behind everything I've done today.

I have one of the most nonresponsive witnesses I've ever deposed in my life. I feel like the deposition has been obstructed to a great extent, and I'm doing the best I can.

I'm not raising my voice. And I'm not yelling. And I think that my request to not lead the witness with speaking objections

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is reasonable.

MS. DAVIDSON: I did not lead the witness in any way, and you know that. I was asking you to please be polite, not badger him, and just simply ask questions and answers, which would make the deposition go more quickly.

You're concerned about eating up time, but you're eating up time berating the witness.

BY MR. SLATER:

Q. Show me where it says Impurity K in the e-mail. I just -- I might have missed that.

A. Impurity K is in the patent, which was attached to the e-mail.

MR. SLATER: We can take that down.

I just need to know if you guys are going to say you need a break again, because I'm going to go into something else.

If you need a break, you can

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do it now. Otherwise I'd like to start and not stop in three minutes.

MS. DAVIDSON: I've been trying to take a break about every hour, and I believe we came back at 2:05. So I was not going to ask for another break for 15 minutes.

Unless Dr. Afnan needs one now. He's the one who should be the guide of it.

THE WITNESS: Let's go for another ten minutes, please.

MR. SLATER: I'm just putting up the next exhibit.

- - -

(Whereupon, Exhibit Afnan-10, No Bates, FDA Statement on the FDA's Ongoing Investigation Into Valsartan and ARB Class Impurities and the Agency's Steps to Address the Root Causes of the Safety Issues, was marked for

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identification.)

- - -

BY MR. SLATER:

Q. On the screen is what we have marked as Exhibit -- I think we're -- on the screen is Exhibit-10, which is an FDA statement dated January 25, 2019.

Do you see that?

A. Yes.

Q. Is this something you relied on in forming your opinions in this case?

A. It is quoted in my -- in my testimony, so yes.

MR. SLATER: Let's go to the second page, third paragraph. Blow it up a little bit.

I'm just going to go -- the paragraph that starts, Since then. There we go.

BY MR. SLATER:

Q. I'm looking at the -- let me restart.

Looking now at the second

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page of this e-mail -- rephrase.

Looking now at the second page of this statement, there's a paragraph that starts, Since then, the FDA and additional manufacturers of other ARB medicines have identified more cases of NDMA impurities as well as NDEA impurities.

Do you see that?

A. Yes.

Q. Looking now at the paragraph that starts with, Since then, the second sentence says, We've placed a ZHP facility on import alert to stop all of its API and finished drugs made using ZHP's API from legally entering the United States. We also issued them a warning letter outlining several manufacturing violations, including impurity control, change control and cross-contamination from one manufacturing process line to another.

Do you see what I just read?

A. Yes.

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Q. So in this FDA statement that you relied on, the FDA makes clear that they issued a warning letter to ZHP, correct?

A. Correct.

Q. They made clear that the warning letter outlined several manufacturing violations, correct?

MS. DAVIDSON: Objection.

BY MR. SLATER:

Q. Correct?

A. That's what the warning letter says.

Q. And those violations are cGMP violations identified in the warning letter, correct?

A. Okay. Yes.

Q. They then list, in general fashion, the nature of those cGMP manufacturing violations as including impurity control, change control and cross-contamination from one manufacturing process line to another.

That's what it says, right?

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A. Yes.
Q. So in this statement that you relied on, the FDA made clear, in January of 2019, that they issued an import alert against ZHP and issued them a warning letter identifying several manufacturing violations of cGMP.
That's in the letter, right? That's in the statement, right?
MS. DAVIDSON: Objection.
BY MR. SLATER:
Q. Correct?
A. That's what the letter says.
Q. If you go to the last sentence of this paragraph, it says, Nonetheless, our inspections did reveal systemic problems of supervision that could have created the conditions for quality issues to arise.
That's what the letter says -- that's what the statement says, again, with regard to their inspections of ZHP, correct?
A. That's what it says in the

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letter, yes.
MR. SLATER: We can take that one down.
BY MR. SLATER:
Q. With regard to the import of the warning letter, the warning letter is a serious document, correct?
MS. DAVIDSON: Objection.
THE WITNESS: The warning letter is informal and advisory. That's what the FDA says. FDA doesn't consider warning letters as final agency action. That's what the FDA says.
BY MR. SLATER:
Q. The warning letters are issued only for violations of regulatory significance; that's the position of the FDA, right?
A. There is a sequence to the issuance of warning letters. The sequence is that there is an inspection, there is a response from the firm, then a warning letter is issued if there is

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grounds to do this.
Now, in this particular case, FDA is doing several things.
Number one, FDA is effectively holding ZHP on the hook to complete its investigation. Their warning letter is issued in November of 2018. The inspection was from 27th of July to 3rd of August. They -- ZHP informed FDA, in June, of presence of NDMA and at the same time informed FDA that it had stopped manufacture of valsartan, it had stopped shipping valsartan and it had informed its clients to stop using the API. They have done it twice.
So, effectively, the warning letter is coming pretty late in the day. And that's because FDA is still waiting for the investigation to complete and for ZHP to give the information to them.
When -- the evidence of this is, when ZHP responded, ZHP gave an immediate response and then gave a

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detailed response, FDA came back with some additional questions and very friendly tone asking for, can you speed up some of the questions?
So the warning letter is not a, you know, this is the end of the day. The warning letter is to engage in a dialogue with the agency to get to the root cause of the issue. That's why warning letters are issued.
And, again, the warning letter, according to the regulatory operations manual, is not -- is informal and advisory, and it's not considered warning letters -- you know, they aren't considered to be final agency action.
Q. The FDA never, ever came out and said that the violations identified in the warning letter did not exist and did not occur? The FDA never said that, right?
A. Well, FDA closed the warning letter sometime later, which means it accepted it.

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ZHP had already challenged some of the observations, and ZHP continued to engage the FDA in its response to the warning letter, addressed those issues.

Q. What the FDA did is, they said, now that we've identified these serious systemic problems and we've given you the warning letter, fix them; here is the violations and now you have to fix it and we're reserving the right to take final enforcement action if we want to.

And then three years later, or two years later, they finally said to ZHP, okay, on a going-forward basis, you finally fixed these problems, we're going to finally remove you from the import alert.

That's what actually occurred, right?

A. No.

MS. DAVIDSON: Objection.

THE WITNESS: So the import alert is actually -- you know, the

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import alert has a very specific purpose. And I'm looking for a text out of my report which I will come to.

The import alert is there to prevent potentially violative product getting into the market. And it's also, according to FDA, is to free up its resources so that it can examine other shipments.

Now, it also -- FDA also wants a uniform coverage across the United States, across the country, and also to put the responsibility back on the firm.

So the issue with this is that the import alert, which was initiated, I think, in September, the import alert was put in place on the same day FDA asked for a list of clients of ZHP.

APIs, when they are sold, there is no expiry date for API.

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So when you sell a batch of APIs, the API can be used continuously until they run out.

What FDA wanted to do, very specifically, was to make sure that the drug product manufacturers, who ZHP had no control over, would not ship those products to the U.S.

The fastest, the easiest and the most convenient solution is an import alert.

BY MR. SLATER:

Q. When I read your report, I thought you said something to the effect of once the import alert was lifted, if ZHP wanted to, it could start re -- it could start selling its valsartan again, the valsartan manufactured with the zinc chloride process.

Did you mean to say that in your report, or did I misread your report?

MS. DAVIDSON: Objection.

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THE WITNESS: So the DMF has not been changed. The DMF is there and it's acting. If --

BY MR. SLATER:

Q. So in your opinion, they can --

MS. DAVIDSON: Whoa. He was in the middle of talking, Adam.

THE WITNESS: So if I go back and look at also on the subject of, okay, so what happened and what did they do, Point 98 in my statement says, In the EIR -- this is the 2018 EIR which resulted in a response and warning letter and an import alert -- they investigated, documented that he reviewed the stability protocol for valsartan implemented in 2012 and everything was good.

And he says, And noted that all data reported within specification, and results were similar across the U.S. and

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non-U.S. market.

99. The EIR, the 2018 EIR, noted that ZHP has an established quality unit, consists of quality assurance department and quality control lab. It further noted that the firm has established written procedures for the quality unit covering supplier qualification, training, batch release validation, calibration, investigation, including deviation and product recalls, stability studies and complaints.

So they investigated, as documented, that the quality unit is functioning well.

100. The inspector observed employees' practices, reviewed documents and conducted personal -- personal interviews with various staff members to assess whether the firm's quality system is designed to achieve

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sufficient control over the facility and commercial manufacturing questions.

Through these activities, she observed the quality unit is involved in activities, including but not limited to, review of manufacturing documents and approval, product prior to release qualification and validation activities, deviations and investigation and change control activities.

A lot of what resulted in the warning letter, and a lot of what went on during the inspection, was ongoing investigation.

So looking at 98, 99 and 100, the quality unit of ZHP was on par. It was functioning according to the GMPs.

So the import alert and the warning letter have to be taken

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again in light of the events and in consideration of what was going on. ZHP informed FDA that it had NDMA in its valsartan. FDA came for an inspection, gave them a set of observations, and then an import alert, which effectively was to prevent material from all these drug product manufacturers coming into the U.S., as well as keeping them on hook.

Now, the DMF is still active. The DMF with zinc chloride is still active, because the quality system is functioning properly.

BY MR. SLATER:

Q. Is the import of you saying, after that answer at the end, that DMF, for the zinc chloride process, is still in effect, that if ZHP wants to, it can manufacture and sell valsartan manufactured with the zinc chloride process?

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MS. DAVIDSON: Objection.

BY MR. SLATER:

Q. Yes or no?

MS. DAVIDSON: Objection. Enough with the yes-or-no follow-ups to every question.

THE WITNESS: Sorry. I will not give you a yes-or-no answer. I'll tell you what is there.

ZHP stopped manufacturing using the process that was resulting in NDMA in June of 2018. They immediately stopped.

They started looking at their process. They put it right.

And as I said, the DMF is still active. Are they selling or not? I have no information about that. I know that the DMF is active.

BY MR. SLATER:

Q. Is ZHP permitted, if it wants to, today, to manufacture and sell in the United States valsartan

manufactured with the zinc chloride process; yes or no?
MS. DAVIDSON: Objection.
THE WITNESS: ZHP is allowed to sell valsartan against the DMF which is active.
MR. SLATER: Thank you. We can take a break. We can go off the record.
THE WITNESS: Thank you.
VIDEO TECHNICIAN: We're off the record at 3:10 p.m.
- - -
(Whereupon, a brief recess was taken.)
- - -
VIDEO TECHNICIAN: We're back on the record at 3:36 p.m.
BY MR. SLATER:
Q. I'm showing you what was attached as Exhibit B to your initial report of December 23, 2022, the list of materials reviewed and considered.
A. Yes.

Q. Did you read all those documents?
A. I -- if it's there, I read it.
Q. And it's your testimony if it is there you read it cover to cover, every one of the documents?
A. So some cover to cover, some several times, some I gleaned through.
Q. Did you read all the deposition transcripts listed there completely?
A. I read the deposition transcripts starting when I started on this project, yes.
Q. You read every single one of those deposition transcripts cover to cover?
MS. DAVIDSON: Objection.
THE WITNESS: So I have read those depositions, yes.
BY MR. SLATER:
Q. One of the things I saw you were provided was the expert report and

deposition of David Chesney?
A. Yes.
Q. Did you read those documents?
A. Yes.
Q. Do you know Mr. Chesney?
A. I know of Mr. Chesney. I don't know him as an acquaintance or a friend.
Q. Did you take into account the opinions that he offered during his deposition?
MS. DAVIDSON: Objection.
THE WITNESS: Did I take into account -- I read his deposition.
BY MR. SLATER:
Q. Were any of the things that David Chesney said in his deposition of any significance to you in forming your opinions in this case?
A. So were they of significance? Again, we've been there before. And I said, what do you mean by

"significance," and you said, did I read it?
So my answer is, based on that definition, yes, I read it. Did he -- did I take it into account? Yes, I did.
Q. Was there anything that Mr. Chesney testified to where you looked at it and said, you know, that's something that's important, I'm going to rely on that for my opinion? Anything you can think of?
A. I don't recall.
MR. SLATER: Let's put up the supplemental list, please. I guess that would be a new exhibit, 12?
- - -
(Whereupon, Exhibit Afnan-11, No Bates, Exhibit B-Materials Reviewed and Considered (Amended and Supplemental), was marked for identification.)

- - -
BY MR. SLATER:
Q. So now we marked as Exhibit-11 your amended and supplemental list of materials reviewed and considered.
Have you seen that document?
A. Yes.
Q. Does this list everything that you have seen, as of now, relative to this case?
A. I believe so.
Q. Unless I missed it, I don't see the deposition -- hang on.
No, I take it back. I see on the first page that you saw some deposition transcripts of our -- of the plaintiffs' experts, Dr. Hecht, Dr. Bain, Dr. Najafi and Dr. Plunkett.
You read those transcripts?
A. Yes.
Q. Did reading those transcripts have any impact on your opinions in this case?

A. Did they have any impact? So, obviously, if I read a document, I will have to consider what is being asked and what is being said. And if I consider that in my deliberations, does it have an impact? Yes. Does it have a supreme impact, a perfect impact? The answer is -- is no.
So, again, I've read them. I've read them. I've looked at the questions, and I've looked at the answers.
Q. I'd like you to assume for a second that the information necessary for ZHP to understand the potential formation of NDMA and NDEA in its valsartan manufacturing processes was available and should have been found by the people that were developing that process and then overseeing that process.
In other words, I'd like you to assume that Dr. Hecht and Dr. Najafi are correct and that Dr. Xue is incorrect on that point.

Do you understand the hypothetical I'm putting you in?
MS. DAVIDSON: I'm sorry, my computer froze, and I missed the hypothetical.
Can you read it back?
MR. SLATER: I'll do it.
BY MR. SLATER:
Q. I want you to assume that Dr. Hecht and Dr. Najafi are correct about what ZHP could and should have known about the potential formation of NDMA and NDEA in the manufacturing processes and that Dr. Xue is incorrect as to what ZHP could and should have known, based on what you read in the reports and depositions, okay?
A. Okay.
Q. If that's the case, then ZHP violated cGMP in failing to test for and identify the presence of the NDMA and NDEA, correct?
MS. DAVIDSON: I'm going to object. That's an improper

hypothetical. Incomplete and vague.
THE WITNESS: So I'm looking at the totality of the statements by Dr. Hecht and Dr. Najafi. And there are statements that I simply cannot subscribe to. And yet you ask me to hypothetically accept those as correct.
If I assume those are correct, then I don't even know whether that would exclude Dr. Xue's conclusions.
However, I cannot -- I struggle to accept statements made by Dr. Najafi and Dr. Hecht. That's my struggle.
BY MR. SLATER:
Q. If ZHP could have and should have identified the potential formation of NDMA and NDEA in the TEA with sodium nitrite quenching and zinc chloride processes and then did absolutely no testing to try to identify whether there

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was NDMA or NDEA, they would have violated cGMPs, correct?

MS. DAVIDSON: Objection.

THE WITNESS: If they could have and they should have, that they -- the struggle that I have is, again, as per FDA's statement, nobody knew -- or, let's be specific, neither industry nor the regulators knew, and it's not only FDA it's also the European regulators, they did not know.

And, therefore, if you do not know, since they didn't know, they weren't looking for it.

So, you know, even based on a hypothesis or a hypothetical -- not hypothesis, a hypothetical that a firm knew, what about FDA? Was FDA colluding with them? No. FDA didn't know either because the knowledge of the process was not known at that time. And if it was not known, then they would not

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have tested for it.

In fact, again, as stated by the FDA, the test methods were not there for detecting NDMA because nobody expected that NDMA was being formed in these processes.

BY MR. SLATER:

Q. Is there any state of facts that I can tell you as to what ZHP -- rephrase.

Is there any set of facts that I can present to you as a hypothetical as to ZHP's knowledge about the manufacturing processes specific to the formation of NDMA and NDEA where you would say, well, if ZHP had known that, then, yes, I agree they violated cGMP in connection with those manufacturing processes?

What would I have to show you for you to say, yes, I can say they violated cGMPs?

MS. DAVIDSON: Objection. Vague.

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THE WITNESS: I'm -- I'm stuck at the beginning of your question, where you say any set of facts as hypotheticals. Facts are not hypotheticals. Facts are facts.

So the question is, what facts are there that you would like to present to me and I will respond to it?

My struggle is with hypotheticals. Yes, hypotheticals can go whichever way they are presented. But the case here is not based on hypotheticals.

If I'm in a deposition, my goal, my objective, is for my testimony to be accurate.

BY MR. SLATER:

Q. Is it your opinion that even if ZHP had known that NDMA and NDEA could form in these manufacturing processes, knew how the -- let me ask it differently.

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If Ethicon -- Ethicon, that's funny.

If ZHP knew that -- let me start over.

If ZHP knew that the substances they were using in the sodium nitrite with quenching and zinc chloride processes could have the reactions that they ultimately were proven to have and that NDMA and NDEA could potentially form, as it ultimately did, if they had identified that, if they had identified those potential reactions, identified that those chemicals and substances would be in the process and knew that this could happen, if they knew that and then did not test to see if there was NDMA and NDEA in those -- being produced by those processes, under that hypothetical, would you say that, well, if they knew those things, yes, they violated cGMP by not testing for NDMA and NDEA?

MS. DAVIDSON: Objection.

THE WITNESS: Again, that's

a hypothetical. So I really need to characterize my response correctly.

If any firm knew of its processes resulting in mutagenic properties, I believe that firm would inform the regulators and would not continue production, which is what ZHP did.

BY MR. SLATER:

Q. Taking your response, if ZHP knew that the NDMA and NDEA could potentially be formed but they weren't sure if it was or was not being formed and the only way to know would be to actually test the valsartan that was being produced to see if there was NDMA and NDEA but they never did the test, under that circumstance, would they violate cGMP?

MS. DAVIDSON: Objection.

THE WITNESS: So if a firm, ZHP, knew that NDEA and NDMA were being formed in one of the

processes, then according to the existing quality system requirements of any firm, they would have to raise a deviation, they would have to stop it -- since it was NDMA and NDEA, they would then effectively stop manufacture and stop shipping.

This happened in June 2018 when they became aware. Prior to that, they didn't know.

BY MR. SLATER:

Q. If they understood that it was possible for the NDMA and NDEA to form, if they understood that and understood the potential mechanism of formation that ultimately was proven to have occurred, would cGMPs, at that time, have required ZHP to then do tests then to see if there was NDMA and NDEA being created?

MS. DAVIDSON: Objection. I think this was asked and answered. If it's different, I

misunderstood.

THE WITNESS: So it's worthwhile to look at the way the pharmaceutical industry operates, or is expected to operate.

A firm, ZHP included, would develop a drug substance process away from the manufacturing facility, in an R&D setting. They would investigate the process. They would assess whether the process is likely to produce, specifically, NDMA and NDEA.

And if there is -- their assessment is not effectively looking -- if their assessment says, the potential of forming these impurities is not there, as per GMP practices, there is no obligation to go digging and looking for those impurities.

All of that is documented in ZHP. ZHP documented the process of looking at the process, looking

at potential impurities and actually testing for what they knew and coming up with a list of them which was compliant to FDA requirements.

They submitted that change as a change to the DMF to FDA. That was reviewed by FDA. FDA accepted the change.

That process, then, got -- effectively, in 2018, the client, a potential client -- not a client, a potential client, Novartis, told them that, hey, what is this peak? Let's look at it. They looked at it, they said it's NDMA.

Immediately, they took action of reporting to FDA, stopping the process, stop selling, did the recall, changed the process, submitted the process to the FDA.

That's why the DMF is still

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active. The DMF is active with a change to the process.
BY MR. SLATER:
Q. Can you answer my question, please?
Doctor, can you please answer my question? I would really appreciate it.
A. So that I'm clear, can you please repeat your question? Because I believe I've answered it.
Q. If ZHP -- actually, you know what, I'll ask the court reporter to read it back to you so we'll get it exact.
And I really ask you, can you just answer the question I actually asked you?
COURT REPORTER: I think Jessica was kicked off.
THE WITNESS: I would like to wait until she's back, please.
MR. SLATER: Go off the record.
VIDEO TECHNICIAN: We're off

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the record at 3:56 p.m.
- - -
(Whereupon, a brief recess was taken.)
- - -
VIDEO TECHNICIAN: We're back on the record at 4:04 p.m.
BY MR. SLATER:
Q. If ZHP understood the possible formation of NDMA and NDEA with its valsartan processes -- let me start over.
If ZHP had understood that the substances it was introducing into the valsartan manufacturing processes, specifically TEA with sodium nitrite quenching and zinc chloride, could potentially cause the formation of NDMA and NDEA, were they required by cGMP to test to see if NDMA and NDEA was formed?
MS. DAVIDSON: Objection.
THE WITNESS: So I did respond to that question.
The response was that

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developing the process happens away from the manufacturing facility.
When ZHP was developing the process away from the manufacturing facility, they did consider the formation of impurities. And at that time, as per FDA's statement that neither FDA nor industry understood the pathway for formation of NDMAs, these were not considered nor detected.
So -- and, again, continuing with what I said before, development of a process is not a GMP process, it's a non-GMP. It's not regulated.
Once it is approved by the regulator and it's a process which is validated, then it becomes a GMP process and it's then in the manufacturing markets -- markets process.

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So your question asks -- your question has hypotheticals that, you know, I would have to conclude to do away with all facts and work in the ether of hypotheticals.
BY MR. SLATER:
Q. When the process changes took place, that's governed by GMP, it's called change control, right?
A. Yes.
Q. If, as part of the process changes, ZHP had realized that the chemicals they were using and the substances they were using could form NDMA and NDEA under the conditions of those processes, if they had realized that, were they required, by cGMPs, to test to see if there was NDMA or NDEA in the valsartan?
A. So giving you, again, almost a repeat answer.
For ZHP to actually change their process using a change control

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procedure, they cannot do it in the manufacturing facility.

What they have to do is develop the process away from the manufacturing facility, then validate the process at scale in the manufacturing facility and discard that batch.

Then submit that to the agency, get approval from the agency and EDQM, because that was also the customer, and then proceed to manufacture for the market.

So it's not a case of suddenly one day they decide to implement a change based on a change control. There was two years of investigations and studies carried out before that change control was actually implemented, which was after approval by the FDA.

Q. I'll ask the question differently.

If ZHP had realized, at any point between 2011 and 2018, that their manufacturing processes for the

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manufacture of valsartan, the TEA with sodium nitrite quenching and the zinc chloride process, could potentially be creating NDMA and NDEA, as soon as they made that -- had that revelation that the process could create those genotoxic impurities, would they have been required to test to see if there was NDMA and NDEA?

MS. DAVIDSON: Objection. Same objections.

THE WITNESS: So when they -- when ZHP identified presence of NDMA in its valsartan, it actually stopped manufacture. It informed the FDA. It put a stop at the process on hold. It put the stock on hold. It requested FDA for a recall classification. So they did all of that.

BY MR. SLATER:

Q. That's great. That's not what I asked you, though. I didn't ask

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you when they figured out that it was there.

I said if they figured out that it was possibly forming, did they need to do the tests, at that point in time when they first realized it could possibly be forming, to see if there was NDMA or NDEA in the drug substance; yes or no?

MS. DAVIDSON: I'm going to object, because you interrupted the witness and are asking the same question again. So it's asked and answered.

But please don't interrupt Dr. Afnan.

THE WITNESS: You know, so if I'd like to go to my report. I would like -- because I address this in my report, and I think that is probably -- if you go to Number 80 in my report.

It says, ZHP performed extensive research and testing for

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more than two years before submitting the drug master file amendment containing zinc chloride process. On June 16th, 2011, ZHP issued a summary of its test production using the zinc chloride process that noted overall the crude isomer of the tri production batches were maintained at 1 to 2 percent and there were no individual impurities that were difficult to remove by crystallization and purification. Therefore, the product quality also met the expected requirements.

Likewise, an internal change request form, dated November 27, 2011, stated that the new process solves the problem of production stability and Valine methyl ester condensation and pentanoy reaction and the new reaction system of zinc chloride and DMF for

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tetrazole reaction is developed, which greatly improves the conversion rate of raw materials, improves the yields, reduces -- reduces -- improves and -- it says reduces the heat and reduces the free waste. In addition, by optimizing the saponification condition, the assay of isomer in valsartan crude is reduced and the quality of valsartan is improved.

Through a large number of experimental results about optimizing process and combined with theoretical analysis, the synthesis route of new process and critical process parameters are initially -- initially determined by Huahai and the preliminary analysis and evaluation of impurities in the new process is completed, confirming that the quality product risk is controlled.

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At the same time, the safety risk brought by process changes are also evaluated by Huahai confirming that the new process is safe and reliable, essentially.

According to the above analysis, the zinc chloride process is stable and reliable and has the conditions for further validation of production. The changes of original process are applied and a new process validation is organized.

And all of this was submitted to FDA.

BY MR. SLATER:

Q. Answer my question, please.

I'm going to ask you now -- I know your counsel is not going to tell you that what you just did is completely obstructive and not responsive. I realize that. I'm just -- I'm just telling you that this is not appropriate.

I asked you a question.

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Your counsel is making crazy faces. I don't know why.

I asked you a very straightforward question and you went and read me this whole section of your report for five minutes. I'm not really sure why you think that's beneficial to your position here.

So can you now answer my question? Which what you just read has nothing to do with.

Can you please answer my question?

A. What was your question?

Q. It's literally a yes-or-no question, a very straightforward hypothetical.

Can you just answer it, please?

MS. DAVIDSON: There's no question pending. He answered the question you asked.

If you want to ask another question, please go ahead.

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BY MR. SLATER:

Q. I asked the question.

Doctor, please just answer it. Come on.

MS. DAVIDSON: Objection. If you want him to answer a question --

MR. SLATER: Don't tell me to ask a question, please. Don't give me instructions. I don't need to be told what to do.

MS. DAVIDSON: There's no question pending. You asked a question. He answered it.

MR. SLATER: I don't want to talk to you. I don't want to speak to you. It's not helpful. It's wasting more time.

BY MR. SLATER:

Q. So, Doctor, answer my question, please.

MS. DAVIDSON: Unfortunately, I'm the person defending this deposition. You're

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interrupting me. You're being rude.
Dr. Afnan answered your question.
If you have another question, ask another question. But you can't just say, I don't like your answer, give me another one.
MR. SLATER: All right, counsel. You stand behind that being responsive. That's fine.
BY MR. SLATER:
Q. Now, Doctor, answer my question.
If ZHP, at any point between 2011 and 2018, realized that their manufacturing processes for valsartan could potentially be creating NDMA and NDEA and they realized what the potential mechanism of formation was, at that point, were they required to test to see if there was NDMA or NDEA in the valsartan; yes or no?

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MS. DAVIDSON: Objection.
THE WITNESS: I'm afraid I can't give you a yes-or-no answer. So I'll give you an answer.
The answer is, based on the hypotheticals that you have posed and the assumptions that you have made, the answer would be yes.
But this is not the case here. I do not subscribe to the hypotheticals. And I do not subscribe to the assumptions.
And, again, this was not the case here with ZHP prior to June 2018.
BY MR. SLATER:
Q. There came a date when Novartis advised ZHP that Novartis thought there might be NDMA in the valsartan, correct?
A. Sorry. Can you ask the first part? It just got cut out.
Q. Novartis notified ZHP, in 2018, that it believed that there might

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be NDMA in ZHP's valsartan, correct?
A. Novartis informed ZHP that -- on 6th of June, informed ZHP that they had asked -- to investigate an unknown impurity. ZHP also, in parallel, started an investigation of that same issue.
So it was actually then that they both came to the same conclusion. And Novartis actually doesn't say here NDMA, Novartis says this is potentially NDMA.
Q. Could ZHP have figured out that there was NDMA in its valsartan without Novartis's involvement? Would that have been possible for ZHP to do that all by itself?
MS. DAVIDSON: Objection.
THE WITNESS: This was a manufacturing process which had been approved by the Europeans and FDA. The analytical method was effectively GC FID that was not detecting NDMAs.

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FDA says that. The methods were not there. And nobody knew about the formation of NDMAs in valsartan, so.
BY MR. SLATER:
Q. Is an important part of the basis for your opinion what the FDA said in the statements that it issued about this situation, about what people knew and what people didn't know, and different methods and all the things that the FDA has said? Is that an important part of your opinion?
A. Yes.
Q. Could ZHP have figured out that there was NDMA in the valsartan without Novartis's assistance? Was that possible, that they could have done it on their own?
MS. DAVIDSON: Objection.
THE WITNESS: The question is whether ZHP could have identified it? And the answer is, what was the justification to go

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and look for it?
Novartis had a reason to look for it, based on what has been shared, which is, here is a little peak which is coming up, and unknown impurity after targeting, and it was below the .1 percent and Novartis said, can we look at that one?
Now, there were other unknown peaks as well, which Novartis did not look at. But Novartis decided to look at that.
BY MR. SLATER:
Q. ZHP could have noticed that peak and investigated that peak without being told anything by Novartis; that was possible, right?
A. ZHP was operating according to Q3A, which said you can have unknown impurities below .1 percent.
So the answer is, they could have. But they had no reason, no justification, no cause to look for that

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impurity and that peak.
Q. If ZHP had been more careful than it actually was and had decided to investigate that NDMA peak, which it had not identified yet, ZHP could have figured out that it was NDMA, right? That was something that was technically feasible for it to do, correct?
MS. DAVIDSON: Objection.
THE WITNESS: So if you know what you're looking for, it is feasible to do it. ZHP looked with GCMS and actually -- so that's how the conversation with Novartis started.
Novartis asked for, can you send the data, the spectra for that peak? Which they did and they sent in. And that effectively was not NDMA; that was the conclusion that they both came to.
BY MR. SLATER:
Q. Were the people at Novartis

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just a lot smarter than the people at ZHP?
MS. DAVIDSON: Objection.
BY MR. SLATER:
Q. Is that why they figured it out and ZHP didn't?
MS. DAVIDSON: I'm sorry. I objected after the first question because I thought there was just one question. And then there was a second question.
I object to both.
THE WITNESS: I cannot comment whatsoever on that. That's beyond the scope of my work, to guess who is smarter.
BY MR. SLATER:
Q. ZHP could have looked at the unknown peaks and could have investigated them and could have figured out that one of those peaks represented NDMA if it had chosen to do a thorough investigation like Novartis did, correct?
MS. DAVIDSON: Objection.

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BY MR. SLATER:
Q. ZHP had the ability to do that if it chose to go through that process, correct?
MS. DAVIDSON: Again, I keep objecting after one question and then a second question gets asked.
I'm objecting to both.
THE WITNESS: ZHP had no reason to investigate, because they were adhering to the GMPs and the requirements of FDA and EDQM. They were following the GMPs.
And, therefore, what was going on was that you were allowed -- or ZHP was allowed to have unknown impurities below .1 percent. This is common practice in industry.
BY MR. SLATER:
Q. You keep explaining this to me. It's a very simple question.
Could ZHP have identified the NDMA peak without Novartis's help if

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ZHP had actually gone through the thought process that Novartis did? Was that possible?
MS. DAVIDSON: Objection. Asked and answered.
THE WITNESS: It's a simple question, and you don't like my answer.
Because my answer is, there was no cause for ZHP to investigate the unknown peaks. There had been no cause from the regulators to investigate those unknown peaks, not -- two regulators.
BY MR. SLATER:
Q. Then why did Novartis investigate the unknown peaks?
A. Novartis was -- sorry.
THE WITNESS: Jessica?
MR. SLATER: Are you asking for an objection, Doctor? I mean --
THE WITNESS: If she wants

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to.
MS. DAVIDSON: He was apologizing for the fact that I had asked earlier to wait before he answered questions.
I would have objected to the question. But go ahead.
MR. SLATER: I have another question. I'm sure you would have.
BY MR. SLATER:
Q. Did Novartis do something that was super human in the pharmaceutical field --
MS. DAVIDSON: Objection.
BY MR. SLATER:
Q. -- that no other company would have ever done, but we just -- everybody just lucked out that Novartis happened to get involved?
MS. DAVIDSON: Objection.
BY MR. SLATER:
Q. Answer the question, please; yes or no.

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A. I can't answer whether Novartis was super human or not.
Q. Okay. Then you can't answer the question. That's fine.
Doctor, one of the very important foundational assumptions in your opinion is that Q3A allowed the NDMA peak to go uninvestigated because it was below .1 percent.
Do I understand that opinion correctly?
A. No, you do not understand that correctly. I have never said that Q3A allows NDMA to be ignored.
If you see it in Q3A, I would appreciate you showing it to me.
Q. You've told -- you've told me that the NDMA peak was so small and it was below .1 percent, so ZHP was not required to investigate what the cause of that peak was; that's your opinion, right?
MS. DAVIDSON: Objection. That completely mischaracterizes

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his testimony.
THE WITNESS: It does. No, that's not what I said.
BY MR. SLATER:
Q. Okay. So was ZHP required to investigate what was behind that peak that ultimately turned out to be NDMA under cGMP; yes or no?
A. I have responded to that question.
Q. Yes or no?
MS. DAVIDSON: Objection. Yes or no is not a question.
THE WITNESS: Yeah, I cannot give you a yes-or-no answer. And the response I've given you, you don't like.
BY MR. SLATER:
Q. That's fine.
MR. SLATER: This is Exhibit-12, right? Just let me know when you know.
MS. DAVIDSON: Are you talking to us?

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MR. SLATER: No, I'm not talking to you.
MS. DAVIDSON: Okay.
- - -
(Whereupon, Exhibit Afnan-12, No Bates, 10/25/06 Impurities in New Drug Substances Q3A(R2), was marked for identification.)
- - -
BY MR. SLATER:
Q. This is Exhibit-12.
A. Yes.
Q. We've put on the screen the ICH Q3A.
Do you see that?
A. Yes.
Q. That's the Q3A that you've been -- or the Q3 that you've been referring to the whole deposition, right?
A. Yes.
MS. DAVIDSON: Objection. Please, Dr. Afnan --
THE WITNESS: Yes.

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MS. DAVIDSON: -- give me time to object.
BY MR. SLATER:
Q. Even though this says that it's impurities in new drug substances, you're aware that there's a guidance for industry, from June 2009, that indicates that this is also applicable to ANDAs, right?
A. Please tell me which guidance.
Q. Let me just ask you this way: You, as the expert on GMP, do you know whether or not this guidance is also applicable not only to new drug substances but also to ANDAs?
A. Q3A, right?
Q. Yep.
A. Yes, it is.
Q. Okay. This is an important document that you're relying on in forming your opinions, right?
A. Yes.
Q. Let's go to Page 2, Section

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3.1.
Under Section 3, which is titled, Rationale for the Reporting and Control of Impurities, there's 3.1, Organic Impurities.
Do you see that?
A. Yes.
Q. This says, The application -- The applicant should -- rephrase.
3.1 says, The applicant should summarize the actual and potential impurities most likely to arise during the synthesis, purification and storage of the new drug substance. This summary should be based on sound scientific appraisal of the chemical reactions involved in the synthesis, impurities associated with raw materials that could contribute to the impurity profile of the new drug substance, and possible degradation products.
Do you see that?
A. Yes.

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Q. So according to this standard, among other things, ZHP was required to make a sound scientific appraisal of impurities associated with the raw materials, correct?
A. Yes.
Q. And, for example, with DMF that would include dimethylamine; that would be an impurity associated with a raw material, right?
MS. DAVIDSON: Objection.
BY MR. SLATER:
Q. Right, Doctor?
A. Okay. Yes.
Q. Possible degradation products, that's another thing that this required ZHP to make a sound scientific appraisal of, right?
MS. DAVIDSON: Objection.
THE WITNESS: They did.
BY MR. SLATER:
Q. That's what this document says they were required to do.
I didn't ask what they did,

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Doctor. So let's now start answering my questions, when I'm down to a few hours.
A. Okay.
MS. DAVIDSON: Objection. If that's a question.
BY MR. SLATER:
Q. It says, They were also required to make a sound scientific appraisal of possible degradation products, correct?
MS. DAVIDSON: Objection. Misstates the document.
BY MR. SLATER:
Q. That's what it says, right?
MS. DAVIDSON: Objection.
THE WITNESS: It says, The summary should be based on sound scientific appraisal of the chemical reactions involved in the synthesis, impurities associated with the raw materials that could contribute to the impurity profile of the new drug substance, and possible degradation products.

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BY MR. SLATER:
Q. Look down now two more paragraphs.
There's a paragraph at the bottom of this section that starts --
MR. SLATER: You've got to scroll down a little bit, Chris.
BY MR. SLATER:
Q. Looking now at the last paragraph in Section 3.1, it says, Identification of impurities present at an apparent level of not more than, less than or equal to, the identification threshold is generally not considered necessary.
Do you see that?
A. Yes.
Q. And that's one of the important things that you've been relying on throughout your testimony today as to why you believe ZHP did not have to do any tests to identify the peak that turned out to be NDMA, correct?
MS. DAVIDSON: Objection.

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That misstates his testimony again.
BY MR. SLATER:
Q. Correct?
A. I do not rely only and solely on this statement which you have here.
I believe ZHP did do a thorough job of looking at its processes.
Q. Did ZHP ever, to your knowledge, try to figure out what the peak was, the one that was NDMA, that we later learned was NDMA, did they ever try to identify what that peak was before Novartis got in touch with them; yes or no?
It's a factual question, did they or didn't they?
MS. DAVIDSON: Objection.
THE WITNESS: The answer is right at the top of the page. If you scroll to just below 3.1, please.
BY MR. SLATER:

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Q. Doctor, I asked if they tried to identify what that peak was. This document doesn't talk about ZHP.
Did they try to identify what that peak was or not; yes or no?
MS. DAVIDSON: You interrupted the witness. And I'm objecting.
MR. SLATER: How about you ask your witness, please, to answer the question directly, as opposed to asking to talk about this document where the answer is not found.
THE WITNESS: You point me to this document and you said, based on this, they should have. And I'm pointing --
BY MR. SLATER:
Q. That's not what I asked you. My question was very direct, Doctor.
I asked you is --
A. You --
Q. -- there anything that

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you've seen indicating that ZHP ever tried to identify what that NDMA peak was before June of 2018?

A. The applicant should summarize the actual and potential impurities most likely to arise during the synthesis, purification and storage of the new product. This summary should be based on sound scientific appraisal.

They did do that.

Based on that -- based on that scientific appraisal by ZHP over two years, as I have read to you a few minutes ago, maybe ten minutes ago, as I read that, this was done.

Q. So you're saying that ZHP actually evaluated the unknown peak that later turned out to be NDMA --

MS. DAVIDSON: Objection.

BY MR. SLATER:

Q. -- to try to figure out what it was before June of 2018?

MS. DAVIDSON: Objection.

THE WITNESS: That's not

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what I said.

BY MR. SLATER:

Q. Well, how about you just give me a straight answer to the question. I don't understand why you can't just say yes or no.

Did they or didn't they try to identify that peak?

MS. DAVIDSON: Objection.

THE WITNESS: There was no regulatory requirement, there was no scientific obligation to identify the peak.

The reason was because they looked at the process, and based on the process, which they looked at, the prediction was that there is no undesirable impurity present in this process. Therefore, the unknowns would not be required to be investigated.

BY MR. SLATER:

Q. Did ZHP ever, to your knowledge, try to identify what that peak

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was that turned out to be NDMA before Novartis got in touch with it?

As a matter of fact, yes or no, did they actually focus on that peak and try to identify what it was at any point before Novartis raised an issue about it; yes or no?

MS. DAVIDSON: Objection.

THE WITNESS: There were customer requests about peaks -- unknown peaks which was -- this was one of them that ZHP had shared information with.

Even with this peak, which is effectively a peak on top of another one, was requested by Novartis, and ZHP provided the information to Novartis.

So did they try? Yes.

BY MR. SLATER:

Q. Did other customers identify that peak and ask what it was, the NDMA peak, at any point before Novartis did in 2018; yes or no?

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MS. DAVIDSON: Objection.

THE WITNESS: If you had allowed me to complete my response, I would have told you that this was not a question about is it an NDMA or not.

The question was, can you provide us with the data as to what this peak is? And ZHP investigated, reported it to them, and they accepted it.

BY MR. SLATER:

Q. Who?

A. The clients.

Q. Which one?

A. There were multiple questions that came from different clients, and that's what they did.

Q. Multiple clients asked questions about unknown peaks, including that peak that turned out to be NDMA?

MS. DAVIDSON: Objection. Misstates his testimony.

Dr. Afnan, give me a minute.

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MR. SLATER: I'll withdraw that question, actually.
MS. DAVIDSON: Okay.
MR. SLATER: We'll live with the testimony.
BY MR. SLATER:
Q. All right. Let's go back to the document.
Looking at the paragraph at the end of 3.1, it says, Identification of impurities present at an apparent level of not more than, less than or equal to the identification threshold is generally not considered necessary. However, analytical procedures should be developed for those potential impurities that are expected to be unusually potent, producing toxic or pharmacological effects at a level not more than, less than or equal to the identification threshold. All impurities should be qualified as described later in this guideline.
Do you see what I just read?

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A. Yes.
Q. The potential impurities that are expected to be unusually potent would include N-nitroso compounds, correct?
MS. DAVIDSON: Objection.
THE WITNESS: N-nitroso compounds are compounds of cohorts of interest.
BY MR. SLATER:
Q. Let's go to Page 4, Section 6.
Looking at Section 6, Listing of Impurities and Specifications. I want to go now to the second paragraph.
About halfway down that paragraph, it says, For impurities known to be unusually potent or to produce toxic or unexpected pharmacological effects, the quantitation/detection limit of the analytical procedures should be commensurate with the level at which the impurities should be controlled. For unidentified impurities, the procedure

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used and assumptions made in establishing the level of the impurity should be clearly stated.
Do you see that?
A. Can you point me to where it is in the second paragraph which begins with, A rational?
Q. Correct. Seven lines down.
A. For impurities known to be -- okay.
Q. That's what the document says, correct?
A. For impurities known to be unusually potent or to produce toxic or unexpected pharmacological effects, the quantitation/detection limit of the analytical procedure should be commensurate with the level at which the impurities should be controlled.
Yes, that's what it says.
Q. Now, let's go to Page 10, which is Attachment 3, the decision tree for identification and qualification.
You cited this in your

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report, right?
A. Yes.
Q. I'm just trying to find where you cited this.
Do you know where this is in your report?
A. No.
Q. All right. Well, that's fine. I don't need to find it in your report.
Do you see at the top -- rephrase.
Do you see at the top of the decision tree, the first input says, Is impurity greater than identification threshold?
A. Yes.
Q. And it says, No. And if you go to no, No action.
And if, Yes, then you go down to the next question of structure identified.
Do you see that?
A. Yes.

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Q. Do you see the little C next to the word "threshold" up at the top?
A. Yes.
Q. Yep. And then on the next page, let's go to the next page, Footnote C says, Lower thresholds can be appropriate if the impurity is unusually toxic, correct?
A. Correct.
Q. So ZHP was required to know that if it turned out that those peaks that were below .1 percent represented unusually toxic substances, like N-nitroso compounds, that they couldn't rely on the threshold of .1 percent; they were required by cGMP to know that, because that's what it said in the Q3A, correct?
MS. DAVIDSON: Objection. Mischaracterizes the document.
THE WITNESS: So if I go back to the very first item that you showed me in this set, in this line of questioning, it says, For

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potential impurities that are expected to be unusually potent, for potential impurities that are expected to be unusually potent.
If ZHP did not know that that was a mutagenic impurity, how would they conclude this is a potent compound?
The same goes for the second statement on Page 4, which says, For impurities known to be unusually potent or produce toxic or unexpected effect.
Again, there is an assumption in your questioning that this unknown impurity was potent.
BY MR. SLATER:
Q. Is the standard objective, meaning we're going to hold all manufacturers to a high standard, or is it subjective, meaning, well, if this manufacturer was really diligent and figured out that there was a potential

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issue, they're held to a higher standard than an unusually less knowledgeable manufacturer that doesn't figure it out and doesn't realize, oh, there is this potential impurity, they're held to a lower standard?
Is that how it works?
MS. DAVIDSON: Objection.
BY MR. SLATER:
Q. It's a yes-or-no question. I just want to know if the same standards apply to everybody.
MS. DAVIDSON: I don't know if that's another question, but if it is, I'm objecting to that one, too.
THE WITNESS: So, again, I do not understand the basis of your question or your assumption of ZHP knew that these were potent and toxic impurities. ZHP did not know that.
When ZHP found that, when ZHP understood that they had NDMA,

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they took all the right actions.
FDA didn't know in -- prior to June 2018, prior to ZHP writing to them and saying, hey, we have NDMA present. FDA didn't know that these unknown impurities in valsartan which, according to FDA, there were about 20 API manufacturers, FDA didn't know these were potent substances.
MR. SLATER: Let's go to the next exhibit, which is the FDA guidance for industry, Genotoxic and Carcinogenic Impurities in Drug Substances and Products, Recommended Approaches, December 2008. Let's go to Exhibit-13.
- - -
(Whereupon, Exhibit Afnan-13, No Bates, Guidance for Industry Genotoxic and Carcinogenic Impurities in Drug Substances and Products: Recommended Approaches, was marked

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for identification.)

- - -

BY MR. SLATER:

Q. Have you ever seen this document?

A. It's a draft document. It's a draft which then eventually -- so, yes, I have.

Q. Are you aware that ZHP cited to this document in its DMFs as being applicable to the manufacturing processes for valsartan?

MS. DAVIDSON: Objection.

THE WITNESS: No, I'm not aware that ZHP referenced this in their DMF applications. I have not come across that statement.

BY MR. SLATER:

Q. Did you consider this guidance for industry and its contents in forming your opinions in this case?

MS. DAVIDSON: Objection.

THE WITNESS: This is a draft guidance, which is dated

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2008. It's an ICH guidance which FDA had started working on, and, therefore, it was in the various stages.

This guidance later became a final guidance.

BY MR. SLATER:

Q. Did you consider this guidance in forming your opinions, this document; yes or no?

MS. DAVIDSON: Objection.

THE WITNESS: I considered --

BY MR. SLATER:

Q. So you did not consider this document, correct?

A. This is a draft guidance which is a precursor to M7.

Q. So is the answer, no, I did not take this into account in forming my opinions?

MS. DAVIDSON: Objection.

THE WITNESS: This is a draft guidance dating back to

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2008.

In 2011, this was either still a draft or not in process, one.

As a draft guidance -- as a fully approved guidance, if it was an approved guidance, then it would not be binding on FDA or industry. That's stated on the second or third page of every guidance.

BY MR. SLATER:

Q. Let's go to the introduction, Page 1.

It says, This guidance is intended to inform pharmaceutical manufacturers of the Food and Drug Administration's current thinking regarding genotoxic and carcinogenic impurities in drug substances and drug products, including biologic products, that are regulated by the Center For Drug Evaluation and Research. This guidance provides recommendations on how to

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evaluate the safety of these impurities during clinical development, investigational new drug applications and for marketing applications, new drug applications, NDAs, biologics, license applications, BLAs and abbreviated new drug applications, ANDAs.

Do you see what I just read?

A. Yes.

Q. Do you know if ZHP was aware of this document and felt that it was obligated to comply with it?

MS. DAVIDSON: Objection.

BY MR. SLATER:

Q. Even though it said it's non-binding, do you know what ZHP's position on that was?

MS. DAVIDSON: Objection. When you say "this document," do you mean the draft or the final?

MR. SLATER: Yes. It's the only document on the screen.

BY MR. SLATER:

Q. Do you know what ZHP's

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position was about this in their depositions; yes or no?
A. It says, This draft guidance, when finalized. It was not final, one.
Two, taking into account the same issue, if you look at the second paragraph, it says, This guidance is intended as an adjunct to the ICH guidance for industry, Q3A. I --
Q. Are you refusing to answer my question?
MS. DAVIDSON: Please don't interrupt him.
MR. SLATER: You know what, Ms. Miller, I have to tell you something, you have an obligation, as an officer of the court, to know that your witness is not being responsive. This has gone on all day.
I don't want to ask for more time, but he has sucked hours out of this deposition with these

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nonresponsive answers, objectively speaking. And I think that it would be in your interest as well, to just say give him direct answers to direct questions.
It would help all of us. I'm not looking to come back again. I would really like to finish today.
But if the witness refuses to answer simple questions, it's very frustrating and it frustrates the purpose of the deposition.
BY MR. SLATER:
Q. Do you know what ZHP's position is as to whether the FDA guidance that's on the screen applied to its development and manufacture of valsartan; yes or no?
A. I have not looked at development reports from ZHP, so I cannot make any comments about that.
This would have been applicable -- or the group that would

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have looked at development would have looked at the development in a different facility that I have not looked at, number one.
Number two, whatever ZHP developed was submitted both to EDQM and to FDA. And both --
Q. Go to the top of Page 2.
MS. DAVIDSON: I'm sorry, Dr. Afnan, were you finished?
THE WITNESS: I said -- no, I wasn't.
I said and both EDQ and FDA accepted their application.
BY MR. SLATER:
Q. Look at the top of Page 2, it says, This guidance describes a variety of ways to characterize and reduce the potential lifetime cancer risk associated with patient exposure to genotoxic and carcinogenic impurities, both during clinical development and after approval.
Do you see what I just read?

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A. Yes.
Q. These approaches include, first bullet point, changing the synthetic and/or purification routes to minimize the formation and/or maximize the removal of the relevant impurity.
Do you see that?
A. Yes.
Q. Number -- the second bullet point, Allowing a maximum daily exposure target of 1.5 micrograms per day for the relevant impurity as a general target for marketed products, though higher levels may be acceptable during clinical development. Certain impurities with structural alerts, suggesting particularly high genotoxic and carcinogenic potential, would not be appropriate for this general threshold approach and would need to be evaluated on a case-by-case basis.
Do you see what I just read?
A. Yes.
Q. N-nitroso compounds fall

within that category of impurities that would not be appropriate for the threshold approach, according to this document; you understand that, correct?

MS. DAVIDSON: Objection.

THE WITNESS: I do.

However, at that time, 2008, ZHP had no clue that their process was making NDMA.

BY MR. SLATER:

Q. Let's go to the bottom of the page where it says, Background.

The compounds that have been demonstrated to induce genetic mutations, chromosomal breaks and/or chromosomal rearrangements are considered genotoxic and have the potential to cause cancer in humans. Exposures to even low levels of these impurities may be of significant concern. Therefore, the identification limits provided in ICH Q3A and ICH Q3B may not be acceptable for genotoxic or carcinogenic impurities.

Do you see what I just read?

A. Yes.

Q. Going a little further down, about four lines further down, it says, Although genotoxic and carcinogenic properties can be acceptable for some active pharmaceutical ingredients, APIs, depending on clinical circumstances, for example, cancer chemotherapies, impurities in drug substances and drug products generally do not have beneficial effects and may impose a risk without associated benefit. Therefore, manufacturers should strive to achieve the lowest levels of genotoxic or carcinogenic impurities that are technically feasible and/or levels that convey no significant cancer risk.

Do you see what I just read?

A. Yes.

Q. And, again, the types of impurities we're talking about would include N-nitroso compounds, and that's what they're talking about in this guidance in 2008, correct?

MS. DAVIDSON: Objection.

THE WITNESS: Yes.

BY MR. SLATER:

Q. Let's go to Page 6.

Section 3 is titled, Recommended Approaches for Initial Assessment of Genotoxic Potential of Impurities.

Do you see that?

A. I do.

Q. The third paragraph under that says, If an impurity that is present at levels below the ICH qualification thresholds is identified, the impurity should be evaluated for genotoxicity and carcinogenicity based on structural activity relationship assessments, i.e., whether there is a structural alert. This evaluation can be conducted via review of the available literature or through a computational toxicology assessment. Commonly used software includes -- and they give examples of the software.

Do you see what I just read?

A. Yes.

Q. And, again, if the impurity, in this case NDMA from the zinc chloride process, had been evaluated, it would have been identified as NDMA and then ZHP would have been duty bound to take action to eliminate it from the valsartan and not sell the valsartan with the NDMA, correct?

MS. DAVIDSON: Objection.

BY MR. SLATER:

Q. I don't know what's so funny, Doctor.

Can you just answer that with a yes or no, please?

A. No, I can't answer with a yes or no.

MS. DAVIDSON: Objection.

BY MR. SLATER:

Q. Fine. You can't answer with a yes or no, I'll move to the next question.

Let's go to Page 7.

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Section 4 is titled, Recommended Approaches for Handling Genotoxic and Carcinogenic Impurities.
And then Section A under that is titled, Prevention of Genotoxic and Carcinogenic Impurity Formation.
Do you see that?
A. Yes.
Q. Prevention of genotoxic and carcinogenic impurity formation is important in drug manufacturing, correct?
A. Yes.
Q. You always want to prevent the formation of genotoxic and carcinogenic impurities when you're manufacturing drug substances, correct?
MS. DAVIDSON: Objection.
THE WITNESS: So, again, this guidance -- this draft guidance, which was published in 2008, ZHP's process in 2007 was actually the TIN process.
ZHP's process was investigated when they changed to

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the TEA and also when they changed to the zinc chloride process.
And they looked, they assessed whether genotoxic impurities would be formed and they concluded that they're not present.
They were going from an existing process, which was the TIN process, to the TEA process and then to the zinc chloride process. So what you're reading to me out of this draft guidance dated 2008 has an assumption that if a manufacturer knew that it has, effectively, carcinogenic substances in it, would they have an obligation to do what you say here? The answer is yes.
However, ZHP investigated, assessed and decided that it didn't know. FDA vouches for that when FDA says, FDA nor industry knew about the formation, about

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the presence of these mutagenic substances.
BY MR. SLATER:
Q. Look now --
MS. DAVIDSON: Can we --
MR. SLATER: I'm right in the middle of this document. I'm not breaking while I'm going through this document. I'm sorry.
BY MR. SLATER:
Q. Looking now at Section A, it says, under the heading of, Prevention of Genotoxic and Carcinogenic Impurity Formation, Since drug-related impurities presumably provide limited, if any, therapeutic benefits and because of their potential to cause cancer in humans, every feasible technical effort should be made to prevent the formation of genotoxic or carcinogenic compounds during drug substance synthesis or drug product manufacturing.
Do you see that?
A. Yes.

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Q. Do you see what I just read?
A. I do.
Q. And you agree that ZHP needed to make every feasible technical effort to prevent the formation of genotoxic or carcinogenic compounds during the synthesis and manufacture of the valsartan it manufactured, correct?
MS. DAVIDSON: Objection.
THE WITNESS: If ZHP knew of the formation of genotoxic compounds, yes.
This is not the case here. ZHP did not know about the formation of NDMA or NDEA in its valsartan process.
BY MR. SLATER:
Q. Let's flip over to the next page.
MR. SLATER: Actually, no, no. Let's scroll down. Scroll down.
BY MR. SLATER:
Q. Do you see at the bottom of

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the page it says, under B1, the title is, Acceptable Levels to Support Marketing Applications.
Do you see that?
A. Yes.
Q. And that's the thresholds that you've been talking about during the deposition, right?
A. The threshold --
MS. DAVIDSON: Objection.
THE WITNESS: No. The threshold is based on, actually -- this is the threshold for -- in this guidance, for very specific substances. The threshold is what is effectively detectable.
So we're looking at two different things.
You are making an assumption that every impurity is genotoxic in ZHP process and in ZHP product. That's not the case.
ZHP assessed the process. ZHP shared that assessment with

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the regulators, that I do not have any mutagenic substances. ZHP received approval from the regulators that there were no mutagenic substances. FDA bears testimony, publicly, by saying neither the regulator nor the manufacturers knew about the formation of NDMAs nor about -- it calls them unexpected impurities.
BY MR. SLATER:
Q. And they issued a warning letter to ZHP -- and when they made all those statements that you just told me, in the statement from the FDA, they pointed out that they issued a warning letter to ZHP for its GMP violations that allowed these substances to exist in its valsartan; that's also what the FDA did, correct?
MS. DAVIDSON: Objection. Misstates many, many things.
THE WITNESS: No. FDA didn't do that.

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BY MR. SLATER:
Q. Fine.
A. FDA --
Q. You said they didn't do it. Doctor, you answered my question.
MS. DAVIDSON: No, no, Adam. If he has something to finish, you know that -- when you've had witnesses, you have them finish their answers, including Dr. Plunkett, who had very long answers.
Dr. Afnan, complete your answer.
THE WITNESS: FDA --
MR. SLATER: Again, let me say for the record, you're telling your witness to ramble on non-responsively to keep sucking time out of the deposition, as an officer of the court.
MS. DAVIDSON: No, that's not what I'm telling the witness. He's not my witness, first of all.

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He's an expert witness.
MR. SLATER: Let him answer. Do you want --
MS. DAVIDSON: He's in the middle of answering a question. You can't just cut him off, Adam, you know that. You know better than that.
MR. SLATER: Thank you. I know better? You stand behind what's going on in this deposition? I find that hard to imagine, but I guess you do.
BY MR. SLATER:
Q. Do you have something else you want to say, Doctor, in response to my last question?
A. Yes, I do.
MS. DAVIDSON: He was in the middle of the answer.
THE WITNESS: Yes, I do.
MS. DAVIDSON: Do you even recall what you were talking about? Because I don't.

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MR. SLATER: Why are you saying that to him? Why would you suggest to him to say he doesn't remember? Why would you do that? It's inappropriate.

MS. DAVIDSON: I'm asking if he wants the question read back, Adam, because --

MR. SLATER: He doesn't need --

MS. DAVIDSON: -- all of your explosions make it impossible for me to even know where we were. Because you rudely interrupted him, then attacked me and then attacked the witness.

If he can -- if he remembers, great. I don't.

Go ahead, Dr. Afnan.

THE WITNESS: ZHP was issued a warning letter. The warning letter which effectively, as I have said, is informal and advisory, as per FDA. And that

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was issued because FDA needed more information on the conclusion of the investigation.

If you look at the communications after the warning letter between FDA and ZHP, FDA is as interested in the outcome of the warning letter -- of the investigation into the formation of NDMAs as is ZHP.

By that time, if -- you know, there is no product being manufactured, the process is changed -- or the process had stopped and the process was changed later.

So the warning letter is there as an informal iterative action by FDA to actually move the firm to come up with a conclusion of what the pathway for formation of these substances are.

FDA, at no point, states in the warning letter that ZHP has

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been making NDMA in its process since 2007 or '10 or '11 or whatever. It's not there.

MS. DAVIDSON: All right. Are we ready for a break? I think everybody needs a break.

MR. SLATER: No, I'm not done with this document, and I'm not breaking.

MS. DAVIDSON: I'm not familiar with the rule that you can go on with a document forever to prevent people from taking a break and going to the bathroom.

THE WITNESS: I am ready for a break.

MR. SLATER: You guys, if you want to stop, even though I'm asking you not to stop, I can't physically stop you.

So you tell me what you want to do. I'd like to continue. If you want to make me stop --

MS. DAVIDSON: Do you -- I

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would like to be cooperative.

Do you have more than five minutes left on this document?

MR. SLATER: I don't know, because every question I ask, I get a long, rambling nonresponsive speech. So I would say, yes, less than five minutes if I get responsive answers to questions.

MS. DAVIDSON: Adam, that's not necessary. If you have more than five --

MR. SLATER: Yes, it is.

MS. DAVIDSON: If you have more than five minutes on the document, I think we should take a break.

MR. SLATER: I don't. I don't have more than five minutes.

You just asked me. I don't have more than five minutes on the document. You can ask the expert that you hired whether or not he could answer questions with a

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direct answer. You're wasting my time on this video.
MS. DAVIDSON: You're wasting it. So let's --
MR. SLATER: What do you want to do, break or not break? Make a decision, please.
MS. DAVIDSON: I would like to have a break and go to the ladies room.
THE WITNESS: Yes, please.
MR. SLATER: Off the record.
VIDEO TECHNICIAN: We're off the record at 5:02 p.m.
- - -
(Whereupon, a brief recess was taken.)
- - -
VIDEO TECHNICIAN: We're back on the record at 5:07 p.m.
BY MR. SLATER:
Q. Looking at --
MR. SLATER: Where is the document?

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BY MR. SLATER:
Q. Looking at Section B1, titled, Acceptable Levels to Support Marketing Applications. Let's go to the carryover of that paragraph on the top of Page 8.
And after they talk about various threshold levels, they state, at the end of that paragraph, at the top of the page, However, there are some compounds containing certain structural groups, aflatoxin-like, N-nitroso and azoxy structures, that have extremely high carcinogenic potency and are excluded from the threshold approach.
Do you see that?
A. Yes.
Q. That includes NDMA and NDEA, correct?
A. Yes.
Q. So if FDA, in its guidance in 2008, said NDMA and NDEA are excluded from the threshold approach; that's what that means, correct?

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A. Yes.
Q. Let's go to Page 13.
Appendix A to this document is the decision tree flow diagram.
Do you see that?
A. Yes.
Q. At the very top it says, Identify impurity.
Do you see that?
A. Yes.
Q. That's the first thing the manufacturer is supposed to do, is actually make every feasible technical effort, as I read that language from earlier in the document, to identify the impurity, right?
MS. DAVIDSON: Objection.
THE WITNESS: Only if the expectation is for the impurity to be genotoxic.
BY MR. SLATER:
Q. It says, Once you identify the impurity, observed level exceeds -- let me go back, actually, to what you

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just said.
You're saying that you have to know that you have a genotoxic impurity before you have to look for the impurity and identify it?
Isn't that a little circular, Doctor?
MS. DAVIDSON: Objection.
THE WITNESS: I don't think it is. I think what the requirements are, there has to be an expectation of genotoxic impurities; an expectation of genotoxic impurities.
BY MR. SLATER:
Q. What if you have an understanding of potential formation of genotoxic impurities, you don't expect it to be formed, but you know it might form from the process that you -- that you're using, are you able to say, well, we don't expect it, so we're not going to investigate why it's there, whether it's there or not? Is that acceptable?

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MS. DAVIDSON: Objection.
MR. SLATER: Let me ask it again.
BY MR. SLATER:
Q. You say if it's expected.
What if it's known to be possible, based on an understanding of the chemical process at issue? In that case, are you allowed to ignore identification of the impurity because you don't know for sure that it's been formed, or do you have to actually investigate to see if it's there?
MS. DAVIDSON: Same objections.
THE WITNESS: The answer is, if you expect it to be there, you need to identify it.
In this case, ZHP did not know that it was potentially there or it could potentially be formed.
BY MR. SLATER:
Q. If ZHP knew that it could potentially form, they would have been

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required to test for the NDMA and NDEA, correct?
A. If they expected it to be there, yes. But they did not know. This is not the case here.
Q. Why do you keep changing my question? I did not ask about if they expected it.
In fact, you didn't answer my prior question, Doctor, you evaded it.
What you said -- I asked you a question, and I'll try it again.
A. Okay.
Q. If ZHP didn't expect NDMA to form but knew that it was potentially going to form based on an understanding of the chemical reactions, did ZHP have to test to see if NDMA was forming?
A. It didn't expect it but potentially knew it would be there? To me, both those two are the same.
If you expect it to be there or if you believe, potentially, it is going to be there, you will test for it.

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And, again, that's not what the case is here. ZHP didn't expect it nor did it know potentially it would be there.
Q. Looking at the decision tree, this says, once you identify the impurity, you go to the next question, Whether the observed level exceeds the relevant ICH qualification threshold or is less than ICH qualification threshold but displays a structural alert.
Do you see that?
A. Yes.
Q. So that's telling you, if you identified NDMA or NDEA, even if it was in a quantity less than the ICH qualification threshold, you would then have to go down where it says, yes, and determine, Are you able to prevent the formation of the impurity, correct?
A. Yes. And, again, not the case here.
Q. It's not the case here because ZHP did not evaluate the

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potential formation -- well, rephrase.
It's not the case here because ZHP did not identify the potential for the formation of nitrosamines in its manufacturing process, correct? That's your opinion, right?
A. Yes. ZHP looked at the process and did not predict or estimate or come up with a reason, justification for formation of mutagenic substances.
Q. And the basis of your opinion that ZHP was not expected to identify the potential formation of NDMA or NDEA in these processes is your reliance on Dr. Xue for that point, correct?
A. No, no, no.
MS. DAVIDSON: Objection.
BY MR. SLATER:
Q. So you're now an organic chemistry expert again?
A. No, no. I haven't answered yet.

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MS. DAVIDSON: And I haven't even had a chance to -- to object, because everybody is talking over each other.

I object to that question. It mischaracterizes his testimony.

Also, he started answering, you did not let him finish. And you, again, made a sarcastic retort. Let him answer the question.

THE WITNESS: I am not an organic chemist. I am not responding as an organic chemist, I am not relying solely on Dr. Xue's expertise in this case.

I am looking at what was developed in the early phases in 2010, 2012, 2013, and submitted to the regulators for their review and approval. They did not identify mutagenic substances prior to 2018.

BY MR. SLATER:

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Q. For your opinion that the organic chemists at ZHP were not expected to figure out that there was a potential for the formation of NDMA or NDEA, do you rely on Dr. Xue's opinion that it would not be expected for a chemist to have known or figured that out, or do you have the opinion that the organic chemist did not need to figure that out?

I'm trying to figure out where your basis is to give this organic chemistry opinion.

MS. DAVIDSON: Objection. If that's a question.

THE WITNESS: I'm not --

BY MR. SLATER:

Q. I'll ask it differently, Doctor.

A. No, I --

Q. The question of whether -- the question of whether ZHP's chemists were expected to identify the potential formation of nitrosamines in these manufacturing processes is a question of

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organic chemistry, in terms of an understanding of the literature and what was available out there and what could have been found and identified by organic chemists, correct?

A. Your question had the word "expected to." My response has been and continues to be that ZHP looked at the process and they came to the conclusion that there are no mutagenic substances formed in the process.

Furthermore, this was a change to the TIN process, which went from TIN to TEA and then it went to zinc chloride. The time difference between the TIN and the zinc chloride process was three years.

There was a lot of studies done during that time period, as well as when they changed to TEA. So they did investigate. They didn't see, they didn't predict -- they didn't predict, they didn't estimate, they did not come up with that expectation of, oh, NDMA

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will be formed here.

FDA also looked at the same data, the same information, and the same chemistry, and did not come up with a conclusion of mutagenic substances are formed in this process.

Q. Is that the basis for your opinion that ZHP was not expected to identify the potential formation of nitrosamines?

What you just went through, is that -- I'm just asking you, is that the basis for the opinion?

MS. DAVIDSON: Objection.

BY MR. SLATER:

Q. I don't need you to repeat it.

I just need to know, is that the basis for the opinion?

A. That was not the opinion I expressed.

Q. One of the reasons why you say ZHP was not expected to identify the potential formation of nitrosamines is

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because ZHP did not identify the potential formation of the nitrosamines based on their risk assessment; is that one of the reasons why you give that opinion, because they didn't figure it out?

A. It's based on the risk assessment, as well as the research they have done.

Q. Another basis for your opinion is that the FDA didn't identify that risk of formation of nitrosamines. That's another reason why you say ZHP was not expected to identify that potential risk.

Do I understand that correctly?

A. I'm not using the FDA statement as a reason of saying that's because they didn't find it.

I'm saying, the FDA's statement verifies that they did not find it, they did not have an expectation of doing so.

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I'm not saying that ZHP based their decision on what the FDA had said, because the FDA said this in 2018. I'm saying the statements, two of, in 2018 and 2019, were effectively verifying that ZHP had not looked at the process and said, you know, we expect NDMAs. FDA says, it was not expected to be there.

Q. In terms of your understanding that ZHP was not expected to have been able to identify the potential formation of nitrosamines, is there anything else that you're relying on besides what you just told me, those two points, for that opinion?

A. It's the investigation, which they had done, the assessments that they had done, the reports that they had issued, which effectively said, we've looked at the process and we do not expect any carcinogenic impurities.

The process -- this was a process revision, this was a process update -- or a process change.

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The original process was developed in 2007. Then, as they changed each step, they looked at the potentials of, you know, formation of undesired impurities, and their conclusion was that there is nothing there.

The analytical data supported that they were not finding anything or that there was no NDMA present.

Q. In forming the opinion -- well, rephrase.

I don't need to go over it again.

MR. SLATER: Let's take this document down. And let's go to -- back to the warning letter, okay.

I'm going to go back to the FDA warning letter. I think we used it. Yeah. We used it very early on.

THE WITNESS: Yes, we did.

MR. SLATER: It was Exhibit-2 or 3 or something?

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MS. DAVIDSON: Yeah, let's just make sure for the record we identify what the exhibit number is.

MR. SLATER: Exhibit-4.

MS. DAVIDSON: Thanks.

BY MR. SLATER:

Q. Let's go, in the warning letter, to Page 4.

This is what the FDA said in Section 2, the heading is, Failure to Evaluate the Potential Effect That Changes in the Manufacturing Process May Have on the Quality of Your API.

Do you see that heading?

A. Yes.

Q. The FDA states, In November 2011, you approved the valsartan API process change that included the use of the solvent DMF. Your intention was to improve the manufacturing process, increase product yield and lower production costs. However, you failed to adequately assess the potential formation

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of mutagenic impurities when you implemented the new process. Specifically, you did not consider the potential for mutagenic or other toxic impurities to form from DMF degradants, including the primary DMF degradant dimethylamine. According to your ongoing investigation, dimethylamine is required for the probable human carcinogen NDMA to form during the valsartan API manufacturing process. NDMA was identified in valsartan API manufactured at your facility.

Do you see what I just read?

A. Yes.

Q. So you agree the FDA found a violation of cGMP based on the failure to adequately assess the potential formation of mutagenic impurities when they implemented the new process.

That's what it says on the document, correct?

A. That's what it says on the document, which is written and issued

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with the benefit of hindsight.

Q. The next paragraph says, You also failed to evaluate the need for additional analytical methods to ensure that unanticipated impurities were appropriately detected and controlled in your valsartan API before you approved the process change. You are responsible for developing and using suitable methods to detect impurities when developing and making change to your manufacturing processes. If new or higher levels of impurities are detected, you should fully evaluate the impurities and take action to ensure the drug is safe for patients.

Do you see what I just read?

A. Yes.

Q. So the FDA found, again, a violation of cGMP because ZHP failed to apply analytical methods sufficient to identify these new impurities, and specifically NDMA -- NDMA and NDEA in their valsartan.

That's what the words on the

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page say, correct?

MS. DAVIDSON: Objection. Mischaracterizes the document.

BY MR. SLATER:

Q. It's what it says, right, Doctor?

A. It says, You failed to evaluate the need for analytical -- for additional analytical methods.

Again, it's important to look at the warning letter in the light of events that took place. When ZHP identified presence of NDMA, ZHP took action. They stopped manufacturing. They started investigating. They informed the FDA. They did a recall. They did all of those.

So this, which is issued in November of 2018, is actually there to make sure that ZHP is going to keep its end of the bargain and continue its investigation.

Otherwise, ZHP had stopped production, had stopped shipping, even

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before the import letter was put in place.

Q. Going now to the third paragraph, the FDA states, Your response states that predicting NDMA formation during the valsartan manufacturing process required an extra dimension over current industry practice and that your process development study was adequate. We disagree. We remind you that common industry practice may not always be consistent with cGMP requirements and that you are responsible for the quality of drugs you produce.

Do you see what I just read?

A. Yes.

Q. Did you read that when you wrote your opinion in your report?

MS. DAVIDSON: Objection.

THE WITNESS: Yes.

BY MR. SLATER:

Q. You keep saying to me, for the last however many hours we've been in this deposition, well, the FDA didn't

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find it, so there was no obligation for ZHP to find it.

This warning letter from the FDA tells ZHP that it was their responsibility to identify the NDMA and they failed to do so.

That's what the words on the page say, correct?

A. Again, those are the words on the page. But it has to be taken in the context of what's going on. FDA had received, had shared every document that ZHP did. Every process that ZHP developed was shared with FDA. It was shared through the amendments to the DMF. It was also informed to FDA when the ANDAs were filed with FDA.

So all of those were shared with FDA. This is in the -- with 20/20 hindsight, in November of 2018, after FDA has been to site multiple times, has not found any issues with the quality system. Then a for-cause inspection, which results in this warning letter.

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So it has to be taken in the light of where it is, you know. It's -- it's suddenly ZHP goes from being compliant to noncompliant on 29th of November 2018.

Q. One of the things you've said to me multiple times is, well, this is with the benefit of hindsight, this is looking back with hindsight.

You'd said that a few times to me, right?

A. Yes.

Q. Does the FDA have a warning letter that they also will issue in a different circumstance where they look into their crystal ball and see what someone is going to do in the future and give them a warning letter for future conduct that hasn't happened yet? Is there the crystal ball warning letter also?

MS. DAVIDSON: Objection.

THE WITNESS: Warning letters are issued after an

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inspection and after review of their response to the inspection.

BY MR. SLATER:

Q. Is it your -- rephrase.

In forming your opinions, did you discount the significance of the retrospective analysis of what occurred, including that performed by ZHP and that performed by the FDA, because it was being done in hindsight?

A. Sorry. Could you either rephrase or explain that question to me again?

Q. Sure.

In forming your opinions as to whether or not ZHP complied with cGMPs --

A. Yes.

Q. -- did you discount the significance of the FDA's findings in this warning letter and discount the significance of the findings by ZHP in its own deviation investigation reports because they were hindsight analyses

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looking back on what happened?

MS. DAVIDSON: Objection.

BY MR. SLATER:

Q. I just want to know, yes or no, did you do that?

MS. DAVIDSON: Okay. Again, every single time you ask a question I object and then you have your little colloquy.

I'm objecting to the question, and if that follow up is a question, to that as well.

THE WITNESS: So, again, you know, in June of 2018, when ZHP informed FDA about presence of NDMA, FDA did not issue, immediately, a warning letter and say, you know what, you're done, this is it, go back.

FDA's warning letter is issued after the response. FDA issues this warning letter because the response was not as expected, the response to the 483.

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MR. SLATER: We're now going to put up on the screen Exhibit-14.

- - -

(Whereupon, Exhibit Afnan-14, ZHP00662283-2309, Investigation Regarding an Unknown Impurity (Genotoxic Impurity), was marked for identification.)

- - -

BY MR. SLATER:

Q. This is a draft of the deviation investigation report, draft of Version 1.

Do you see this on the screen? Have you seen this document before?

A. I have seen the final version, yes.

Q. All right. Well, let me go to -- let's go to -- the Bates number is 308 at the bottom right.

A. 308.

Q. Under Section 5.2, it says,

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Control strategy. And the paragraph starts, Due to insufficient extent and depth of process research at the early stage, as well as insufficient study and understanding of potential genotoxic impurities, only side reaction product and degradation products were studied and was unaware of the further reaction between degradation products and raw material.

Do you see what I just read?

A. Yes.

Q. Have you ever seen that before right now?

A. As I said, this is the draft. I've seen the final version.

Q. So you've never seen the language I just read to you, correct?

A. I do not recall reading that language in the final version. But it may --

Q. Now having seen that there were people at ZHP that wrote into a deviation investigation report that they

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had an insufficient extent and depth of process research and insufficient study and understanding of potential genotoxic impurities, and as a result, they failed to investigate and assess all of the reactions, now having seen that, that's an important fact that you need to take into consideration and reassess your opinions as to whether or not they did an adequate assessment of the risks of formation of nitrosamines, correct?

MS. DAVIDSON: Objection.

THE WITNESS: So this is a draft document. The purpose of a draft document is document in progress. It's being developed.

So if you look at the final version, we will see what was there.

A draft is something which is being written by people to be considered as a -- as a group, and an investigation. In pharma it's usually effectively reviewed

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collectively and it's also developed collectively.

So because it was in the draft, it doesn't mean it's in the final version. It doesn't mean it's correct.

I don't know who wrote that. I don't know whether the quality organization of the site agreed with that statement.

BY MR. SLATER:

Q. You agree with that statement, that that's what occurred?

MS. DAVIDSON: Objection.

THE WITNESS: This is a draft. Let's pull up the final version and look --

BY MR. SLATER:

Q. Let's answer my question.

You just said I agree with that statement. You're saying you agree with the statement I just read to you, correct?

MS. DAVIDSON: Objection.

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That mischaracterizes his testimony.
MR. SLATER: Why are you testifying? Please don't.
MS. DAVIDSON: He didn't say that.
THE WITNESS: No, no.
MS. DAVIDSON: You're misquoting him, Adam.
MR. SLATER: Okay. Then I'll ask you the next question.
BY MR. SLATER:
Q. You did not say that.
You know, one possibility is that that is true, that's what actually happened and someone at ZHP said, wait a second, we can't admit in this document, which we're submitting to the FDA, what this says, because it's an admission that we did insufficient research and an insufficient risk assessment, so we need to remove that. That's one possible reason why that language was removed.
You'll -- as an objective

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expert, you would agree that's one possible explanation, right?
MS. DAVIDSON: Objection.
THE WITNESS: That's -- that would be against the GMPs of falsifying records. ZHP was not cited for data integrity and for falsifying records.
BY MR. SLATER:
Q. Did the FDA ever see this document that I'm showing you right now, this draft?
MS. DAVIDSON: Objection.
THE WITNESS: I have no idea. My point is not whether FDA saw this draft or not.
FDA, if they had been presented with a draft, if the investigator would have normally said, give me the final version, not the draft.
BY MR. SLATER:
Q. If what's written there is actually true, ZHP violated cGMPs,

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correct?
If what I just read to you is actually the truth, they violated cGMPs, correct?
A. If what is written here -- again, I go back, and you're not going to like my answer, that, effectively, that development work -- you know, assuming that's a correct statement, the depth of process of research at the early stages, as well as insufficient study and undertaking, would occur at the development location where GMPs do not apply.
So, effectively, development is parceled -- is run at a different location to the -- to the manufacturing facility. That's why development has no GMPs, no -- no rules and regulations covering it. It's effectively best practices.
Q. Pharmaceutical best practices?
You said "best practices,"

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do you mean pharmaceutical best practices?
A. It's the common practice that development is not regulated by any regulator.
Q. The risk assessment -- rephrase.
If the statement I just read is a true statement in characterizing the level of research and understanding during the risk assessment phase of the change control process, which was governed by cGMP, then they violated cGMP, correct?
A. If the level of research was insufficient, it is not contrary to GMPs, it is just a badly developed process.
There are badly developed processes in pharma, in industry, which are there.
Now, specifically if they are looking at, okay, we didn't do the research, or if the statement is a firm did not do their research to then find

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the formation of degradants and degradation products and so on and so forth, and informed the regulator that I have done the work and everything is fine and it's not there, that would be -- in fact, not even GMPs, that would be lying to the regulator.

Q. The guidances we went through earlier talked about the need to take every feasible technical effort to avoid genotoxic impurities.

Remember we talked about that?

A. Yes.

Q. Part of taking every feasible technical effort would be making sure that you have sufficient extent and depth of process research and sufficient study and understanding of the potential genotoxic impurities so that you could understand the potential reactions and avoid those reactions and avoid the impurity, correct?

A. Yes. On the provision that

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you expect to form undesirable impurities.

MR. SLATER: We can take that down.

Let's go -- can you get to Q7A by any chance? I'm sorry, I didn't give you a heads up, Chris.

Got it? Forget it? Here. You take it and when you find it let me know.

MS. DAVIDSON: Adam, do you want to go off the record while you figure this out?

MR. SLATER: Nope. I want to keep moving, one way or the other.

Hey, Chris, can you go to -- put up the EMEA?

All right. Go off the record for a second. I got Chris all screwed up with this.

MS. DAVIDSON: No problem.

VIDEO TECHNICIAN: Hang on a second. We're off the record at

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5:42 p.m.

- - -

(Whereupon, a brief recess was taken.)

- - -

VIDEO TECHNICIAN: We're back on the record at 5:42 p.m.

MR. SLATER: Let's put up Q7A. We're up to Exhibit-15 now.

- - -

(Whereupon, Exhibit Afnan-15, No Bates, Guidance for Industry Q7A Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients, was marked for identification.)

- - -

BY MR. SLATER:

Q. Looking at the Q7A, dated August 2001, that's a document you're familiar with, correct?

A. Yes.

Q. This applied, in your opinion, to ZHP's manufacture of

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valsartan?

A. Yes.

Q. Let's go to Page 1.

Under the introduction, the second paragraph, the third line, it says, In this guidance, the term "should" identifies recommendations that, when followed, will ensure compliance with cGMPs. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes.

Do you see what I just read?

A. Yes.

Can I ask a question? Is there a reason why you're using this version?

Q. Is there a different version you think I should be using?

A. I'm just asking because there is another one which was finalized in 2016.

Q. I thought I would use the one that was in effect the entire time.

A. Sure. Thank you.

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Q. Let's go to Page 28.
Under the heading of, Laboratory Controls, if we go down to the third paragraph, it says, All specifications, sampling plans and test procedures should be scientifically sound and appropriate to ensure that raw materials, intermediates, APIs and labels and packaging materials conform to established standards of quality and/or purity.
Do you see that?
A. Yes.
Q. And ZHP was required to ensure that all of its specifications, sampling plans and test procedures were scientifically sound, right?
A. Yes.
Q. That was a cGMP obligation, right?
A. It is, yes.
The reason I hesitate is because, actually, since this is a generic drug or generic API, there is a

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USP monograph of valsartan which would actually be the specifications for valsartan.
Q. We went through, before, that the USP had explained that you must develop additional tests and analytical methods if you change the process and you're going to introduce external sources that could bring impurities into the process.
Remember we went through that before?
A. I do remember. That's not the one I'm referring to.
There is a monograph for valsartan API.
Q. I realize that.
But the monograph for valsartan API is not the exhaustive list of tests and acceptance criteria applicable once ZHP developed its new processing methods and was introducing external sources that could bring impurities in, like DMF and

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triethylamine, right?
MS. DAVIDSON: Objection.
BY MR. SLATER:
Q. Correct?
A. If --
MS. DAVIDSON: Objection.
THE WITNESS: If ZHP wanted to sell its product to United States, it would have to meet the requirements of the USP monograph for valsartan.
BY MR. SLATER:
Q. And this language I just read, because, remember, we said should, we read that from the beginning, means if you do this, you're going to comply with cGMP.
And they're saying here, you need to ensure that the raw materials, intermediates, APIs, et cetera, conform to established standards of quality and/or purity, right?
MS. DAVIDSON: Objection.
THE WITNESS: It says all

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specifications, sampling plans, test procedures should be scientifically sound and appropriate to ensure that raw materials, intermediates, APIs and labels and packaging materials conform to standards.
I'm not disputing that.
BY MR. SLATER:
Q. And in this case, it turned out that the -- that the valsartan contained NDMA, and, by definition, the established standards of quality and purity did not approve and allow for NDMA to be in valsartan, correct?
MS. DAVIDSON: Objection.
THE WITNESS: So, again, I would like to say that you're -- so the monograph on valsartan does not have NDMA. You're correct, it doesn't have it in there.
But it also stipulates what test methods should be used for -- for assessing the specification,

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the quality of valsartan.
BY MR. SLATER:
Q. We literally just went through this, that non-monograph tests and acceptance criteria are required where you change the processing methods or introduce external sources that could bring impurities to them, then you have to develop other testing and acceptance criteria to address those circumstances.
That's literally what the USP says, right?
MS. DAVIDSON: Objection.
THE WITNESS: No. That's not what the USP says.
It's if you believe that there are undesirable impurities present. Q3A allows you to have less than .1 percent.
This document, which says that it should be scientifically sound, Q7, does not address about bringing in new test methods or whatever. Is --

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BY MR. SLATER:
Q. I --
MS. DAVIDSON: Are you interrupting him? Are you done?
THE WITNESS: No, I'm not done.
MS. DAVIDSON: You're both talking over each other.
THE WITNESS: I'm not done.
So Q7 specifically says, here are the specifications, ding, ding, ding, ding, specifications, sampling plans, test procedures should be scientifically sound and appropriate.
And what I have said is the test procedures are defined by USP monograph of valsartan.
BY MR. SLATER:
Q. You're not testifying that the USP allows -- rephrase.
You're not testifying the USP permitted the valsartan sold by ZHP to have NDMA or NDEA in it? That's not

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what you're saying, is it?
A. That's not what I'm saying, no.
Q. Okay. And you would agree with me the USP did not permit NDMA or NDEA to be in the valsartan, correct?
A. USP does not say in its monograph NDMA should be absent.
Q. It's understood that there should be no NDMA or NDEA in valsartan in order to comply with USP, correct?
A. It's understood and accepted that nitrosamines should not be present in drug product or drug substance at levels which cause concern.
Q. Let's go to the next page, Page 29.
Section B is, Testing of Intermediates and APIs. And the second paragraph says, An impurity profile describing the identified and unidentified impurities present in a typical batch produced by a specific controlled production process should

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normally be established for each API. The impurity profile should include the identity or some qualitative analytical designation, for example, retention time, the range of each impurity observed, and classification of each identified impurity, for example, inorganic, organic, solvent.
Do you see that?
A. Yes.
Q. And that requirement applied to ZHP and required that they identify, in some manner as described here, every one of the impurities that were showing up on their testing, even if they hadn't identified exactly what the impurities are, correct?
A. As per text, it says, An impurity profile describing the identified and unidentified impurities present in a typical batch produced by specific controls should normally be established for each API.
So there should be a purity

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and an impurity profile effectively created for each product. And this was done by ZHP.

Q. Where did ZHP develop an impurity profile that identified the NDMA and the NDEA in its valsartan in accordance with this? Tell me where they were identified -- and I'm going to use the language, either identified by name or some qualitative analytical designation.

Tell me where that was done. What document did that?

MS. DAVIDSON: Objection.

THE WITNESS: So if they had identified NDMA, which they had not, then it would not be listed as an unknown -- unidentified impurity. ZHP had no cause to predict or estimate presence of NDMAs prior to June 2018.

ZHP did develop an impurity profile and -- impurity profile in 2007, which was with the TIN

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process. Then as they did each change, this question was raised, addressed and verified that the impurity profile has not drastically changed, drastically changed meaning some -- you know, effectively, impurity A concentration had gone down as they improved the process. The impurity profile, it stated, did not change.

So both the impurity profile and the purity profile remained unchanged as they went from the TEA process to the zinc chloride process.

BY MR. SLATER:

Q. ZHP specifically said that the impurity profile had not changed and they said that in the DMF for both of the new processes, right?

A. Correct.

MS. DAVIDSON: Objection.

THE WITNESS: Sorry.

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BY MR. SLATER:

Q. In fact, the NDMA and NDEA were new impurities that were never identified either by name or by some qualitative analytical designation anywhere in any document.

They never did that, right?

MS. DAVIDSON: Objection.

THE WITNESS: So ZHP, not knowing that NDMA or NDEA is present in the product, looked at the impurity profile, and the impurity profile effectively says what do you have?

Again, going back to 3A, Q3A, it says, you need to list your known impurity profile, which are listed in the USP monograph, and then look at your impurity profile and the collective sum of those cannot go above a certain limit.

So they looked at it; it was not there. They didn't see it.

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They did not know about NDMA or NDEA.

BY MR. SLATER:

Q. The peaks -- we'll talk about NDMA.

The peak for NDMA was there, they just didn't identify what it was.

We've agreed to that before, right? You've told me it was too small, whatever. But -- let me rephrase.

The NDMA peak was there, it just wasn't identified, and it wasn't identified by name, and it wasn't identified by qualitative analytical designation as described in this ICH guidance; it was never identified, correct?

MS. DAVIDSON: Objection.

BY MR. SLATER:

Q. Either by name or by location or anything else?

MS. DAVIDSON: Objection.

That was a lot of questions.

BY MR. SLATER:

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Q. I'll ask it again, because I know you got a great objection there.
Let's go back to my original question.
Where did ZHP identify the NDMA and NDEA, either by identity or qualitative analytical designation, as required in what I just read?
A. ZHP --
Q. I've never seen the document. Is there a document where that happened?
MS. DAVIDSON: Adam, literally, he started talking and you asked another question.
What are you doing?
MR. SLATER: I'm trying to get him to actually answer my question.
BY MR. SLATER:
Q. I'm asking if there's a document.
MR. SLATER: Why don't you please ask your witness to just

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tell me, yes or no, is there a document where he's seen that.
It's the only question I'm asking.
THE WITNESS: There was --
MS. DAVIDSON: I'm objecting to this colloquy.
Ali, if you know what question is pending, go ahead and answer.
THE WITNESS: There are three or four questions there.
BY MR. SLATER:
Q. I'll ask it again, because you're confused, you think there's three or four questions.
Is there a document you can point me to where ZHP identified, either by name or by qualitative analytical designation, the NDEA and the NDMA; yes or no?
A. ZHP was not aware of NDMA or NDEA until June 2018. Prior to June 2018, ZHP had looked at the impurity profile and the peaks coming, alluding,

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after it had been investigated.
They did not report it to clients unless the clients asked. And when they did their assessment, which was based on GC FID and GCMS pointed to a solvent or solvents that they were using in the process, not DMF, not any of the DMF degradants. There are other processes.
And that is in the communications which went between the clients and ZHP saying, what was that impurity?
That was also the subject of my call with Jucai Ge.
Q. Nowhere in any impurity profile have you seen where ZHP specifically identified each impurity observed and classified each identified impurity as required here? That did not happen, right?
MS. DAVIDSON: Objection.
THE WITNESS: I've answered the question. And I'll answer

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again.
ZHP did not know about NDMA or NDEA until June 2018. ZHP had looked at the impurity profile, and the impurity profile, which would have been filed with the DMF changes, would have said what was there and the fact that the profile was whatever it was.
BY MR. SLATER:
Q. And we both know from reading the DMF that that impurity profile did not mention NDMA or NDEA or identify either of those impurities in a qualitative or quantitative way.
They were not mentioned at all, correct?
A. I'll give a repeat.
MS. DAVIDSON: Objection.
THE WITNESS: ZHP didn't know about NDMA or NDEA in its valsartan process until June 2018. So if it didn't know about the presence of NDMA or NDEA there was

no way for it to actually list them as saying, here is NDMA or NDEA.

It was not expected, it was not detected, the methods that were there were not sufficient to detect them. FDA also agrees with that statement.

MR. SLATER: You can take that document down.

BY MR. SLATER:

Q. You talked about bioequivalence a lot in your report.

Do you know what that means?

A. I hope so.

Q. What does bioequivalence mean?

A. It means it will have the same response biologically as the reference listed drug.

Q. So, for example, with valsartan, in simple terms, it will still have the desired effect on the body to control blood pressure?

A. The same desired effect as its reference listed drug, yes.

Q. Therapeutic equivalent is a different term with a different meaning, correct?

A. Yes.

Q. That means that the drug has the same quality, identity, and purity as the reference listed drug, correct?

MS. DAVIDSON: Did I freeze or did Adam freeze?

THE WITNESS: No, you're not frozen.

BY MR. SLATER:

Q. Correct?

MS. DAVIDSON: I'm sorry, I'm not sure what happened.

Did you say something after the word "identity"?

MR. SLATER: I'll just ask the question again.

MS. DAVIDSON: Okay. I'm sorry. I didn't force my Internet to stop.

MR. SLATER: Can I just talk, please?

MS. DAVIDSON: Sure.

BY MR. SLATER:

Q. Therapeutic equivalent means the drug has the same quality, identity and purity as the reference listed drug, correct?

A. Yes.

Q. And you understand that our claim in this case is not that there was a lack of bioequivalence, you understand that the claim is that there was a lack of therapeutic equivalence?

You understand that, right?

MS. DAVIDSON: Objection.

BY MR. SLATER:

Q. Or do you not understand that?

MS. DAVIDSON: Objection.

THE WITNESS: That's -- I understand what therapeutic equivalence is. I think the question of same quality -- the

quality, as I said earlier, according to USP, is defined to be 98 to 102 percent purity for valsartan.

So that's what it means to me, 98 to 102 percent.

BY MR. SLATER:

Q. With all due respect, all I'm asking you is this: You used the term "bioequivalence," and you said the plaintiffs' experts are criticizing the lack of bioequivalence. You said that many times in your report.

Do you understand that the claim is not a lack of bioequivalence but actually is a claim of a lack of therapeutic equivalence?

I'm just asking if you understand that.

MS. DAVIDSON: Objection.

THE WITNESS: So your -- the plaintiff experts referred to bioequivalence. That's what I have addressed.

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You're muted.
MR. SLATER: Can I have the court reporter read back the answer, please? I lost the feed for a second.
- - -
(Whereupon, the court reporter read the following part of the record:
"Answer: The plaintiff experts referred to bioequivalence. That's what I have addressed.")
- - -
BY MR. SLATER:
Q. You talked in your report about Valisure and testing of Diovan, right?
A. I did, yes.
Q. Are you relying on Valisure's testing of Diovan as a basis for your opinions in this case?
A. Could you just repeat the first part? Am I --

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Q. Are you relying on Valisure's purported findings on testing of Diovan as a basis for your opinions in this case?
A. So Diovan -- Valisure tested a Novartis product. Novartis in United States. That product was the only -- the only valsartan which is approved by -- approved for Novartis is an NDA drug, which is listed as a reference standard and as the ROD.
Valisure tested Novartis product. There is no expectation for this to be a generic sample which it brought to the U.S. and to be tested. Valisure tested it, and the plaintiff expert lab, Emory, Dr. Najafi, he also verified those tests.
Now, I believe -- I am not certain, but I believe that that Diovan was -- or those samples were Diovan. I've asked Skadden counsel for the NDC number, which has been requested but not yet provided.

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If we have the NDC number, that would directly pinpoint to whether it's Diovan or not.
Q. I'll let you assume, for purposes of these next questions, that what Valisure tested was Diovan, okay?
A. Okay.
Q. If that's the case, are you relying on Valisure's testing of Diovan purportedly finding NDMA as a basis for your opinions? Is it something you're relying on as one of the bases for your opinions?
MS. DAVIDSON: Objection.
THE WITNESS: Which opinion?
BY MR. SLATER:
Q. Any of your opinions.
MS. DAVIDSON: The first question --
BY MR. SLATER:
Q. This is really not that complicated. I'm not asking for an explanation or which opinions. It's a very simple question.

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Are you relying on Valisure's testing of Diovan and purported finding of NDMA in Diovan as one of the bases for your opinions in this case; yes or no?
MS. DAVIDSON: Well, first you said assume something. Is the assumption still part of your question?
MR. SLATER: Yes. That they tested Diovan.
THE WITNESS: So there are 212 opinions that I have put in. I really would need to be very careful of saying this applies across the board, because, you know, some of them have nothing to do with Valisure testing. My --
BY MR. SLATER:
Q. I'll ask you a different question.
MS. DAVIDSON: Wait. He was in the middle of talking.
MR. SLATER: Are you just --

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I'm trying to use time wisely here, and you're just wanting to just keep talking on something like this. I mean, what's the point?

MS. DAVIDSON: You can't interrupt a witness. It's, like, Rule 101.

MR. SLATER: Maybe you should interrupt him.

BY MR. SLATER:

Q. Keep going, Doctor.

A. So my point is that Valisure -- you know, the plaintiff experts make the statement saying this drug is not equivalent to Diovan.

The point is, if Diovan has NDMA in it, then what are we talking about? Because -- because even Diovan, if it had NDMA in it, then you don't -- that's a discovery which is made late in the day.

Q. Did you read Dr. Xue's deposition?

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A. I did read Dr. Xue's deposition.

Q. Do you agree with me -- well, rephrase.

Do you agree with Dr. Xue that the chemical -- rephrase.

Do you agree with Dr. Xue that the manufacturing process and the chemical reactions in the TIN process which is used to make Diovan is not capable of forming NDMA?

MS. DAVIDSON: Objection.

THE WITNESS: Can I see that statement from Dr. Xue, please?

BY MR. SLATER:

Q. No, I don't have time to start showing you things. So let me ask the question differently.

Do you assume, in forming -- rephrase.

If the -- rephrase.

If Valisure tested Diovan, and if Valisure reported that they found NDMA based on that testing, you're saying

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that's significant to you because if Diovan had NDMA in it, you said, what are we talking about? Do I understand you correctly?

A. No. My point --

Q. Fine. That's fine. I don't understand you. Next question.

Do you have any understanding or assumption that the testing that was performed by Valisure was reliable?

A. It was verified by the plaintiff expert's lab.

Q. You're assuming that Dr. Najafi's lab actually verified the testing of the Diovan that's referred to by Valisure; yes or no?

A. Dr. Najafi tested the same samples, and according to his deposition, he said that -- first he said, yes, they were the same, and then he said they were in the same ballpark.

So, no he didn't test for Valisure. The results issued or reported

Page 413

on Valisure are not necessarily done by Emory Labs. But Emory Labs tested and agreed with those, according to Dr. Najafi.

Q. Are you aware that the samples that were provided to Dr. Najafi, that the results he reported, don't match up to the results for the Diovan that was tested by Valisure, which shows that he actually tested different blind specimens?

Did you ever look at that and match that up?

MS. DAVIDSON: Objection.

BY MR. SLATER:

Q. I'm just asking, did you ever look at the results to see that they are different?

A. His deposition said that Valisure told him he is in the right ballpark.

Q. Did you ever see the letter from FDA to Valisure dated December 5, 2022?

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A. Yes.
Q. Did you see all of the different problems that the FDA identified with Valisure's testing, including their testing for nitrosamine impurities in valsartan?
A. I do -- I prefer -- I would appreciate if you could show it to me.
Q. I'm just asking, do you remember seeing that the FDA criticized Valisure's testing for nitrosamine impurities in valsartan?
MS. DAVIDSON: Objection.
THE WITNESS: I really would like to see the document before I agree to you.
BY MR. SLATER:
Q. Do you have an opinion that Valisure's testing was reliable and that you're relying on what they say about what they found in Diovan?
Just yes or no, I just want to know.
MS. DAVIDSON: Objection.

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He responded multiple times. He said he wanted to see the letter. You're badgering him and pressuring him.
MR. SLATER: No. What I'm doing is not getting all my time sucked up to show him something that he already knows.
THE WITNESS: I have not looked at Valisure's document --
BY MR. SLATER:
Q. Okay. I'll --
A. No, no, no.
I have not looked at Valisure's GMP systems to make a decision whether it's reliable or not.
Q. Okay.
A. Sorry.
MS. DAVIDSON: If you want him to look at the letter --
MR. SLATER: No, I really don't. I'm going to ask my next question.
MS. DAVIDSON: -- off the

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record. Please don't interrupt me.
I was saying if you want -- I was trying to be gracious.
MR. SLATER: It's okay. We're way past gracious, I'm sorry. I just need to ask my next question.
I don't know why you're making a face. I just want --
MS. DAVIDSON: I just think it's incredibly rude, Adam, how you talk over me. Incredibly rude and shocking.
MR. SLATER: I'm sorry, I don't have a lot of time.
MS. DAVIDSON: While I was offering to go off so that you wouldn't use your time in looking at the document.
MR. SLATER: I don't need to look at the document.
BY MR. SLATER:
Q. Doctor, does the approved

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formulation of Diovan include NDMA in it?
A. Approved formulation? Can you be very specific?
Do you mean what FDA approved or do you mean what is being sold in the market?
Q. What FDA approved.
A. So what FDA approved should not have -- actually, I have no idea, because now it's hindsight. We are looking back.
At the time FDA approved, FDA assumed there was no NDMA. At the time FDA approved ZHP process, there was an understanding that there was no NDMA.
Q. If there would be NDMA in a Diovan pill, that would be due to a cGMP violation in the manufacturing process, correct?
MS. DAVIDSON: Objection. Calls for speculation.
THE WITNESS: I can't make that statement. You know, you want a yes-or-no answer, and I'm

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sorry, I can't give you a yes-or-no answer.
BY MR. SLATER:
Q. Are you aware that the manufacturing process and chemical reactions for Diovan are incapable of forming NDMA as an impurity?
MS. DAVIDSON: Objection.
THE WITNESS: I have not looked at the NDMA process. I am looking at Valisure. I am looking at, effectively, Dr. Najafi saying that, yes, he found it and it's in the -- ballpark agrees with Valisure's data.
BY MR. SLATER:
Q. If I'm correct and Dr. Xue is correct that the manufacturing process for Diovan was not capable of creating NDMA, then the only way for NDMA to get into the pills would be due to a cGMP violation, correct?
A. I cannot --
MS. DAVIDSON: Same

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objections.
THE WITNESS: I cannot comment on Novartis's manufacturing process because I have not looked at it. I don't know what they do.
You obviously have knowledge of the process. I don't.
MR. SLATER: Let's go off the record.
VIDEO TECHNICIAN: We're off the record at 6:14 p.m.
- - -
(Whereupon, a brief recess was taken.)
- - -
VIDEO TECHNICIAN: We're back on the record at 6:22 p.m.
- - -
(Whereupon, Exhibit Afnan-16, ZHP01721348, Genotoxicity Statement, was marked for identification.)
- - -

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BY MR. SLATER:
Q. We've put on the screen Exhibit-16, a genotoxicity statement, dated July 14, 2015, signed by Lucy Liu, manager of regulatory affairs at ZHP.
Have you seen this document?
A. I think I have.
Q. And you can see on July 14, 2015, ZHP represented that its valsartan was, to the best of its knowledge, in accordance with the guideline, the EMEA/CHMP/QWP/251344/2006 and ICH M7.
Do you see that?
A. Yes.
Q. Do you know what the first guideline is that they listed there?
A. It's the quality working party of EMEA.
Q. What's the significance of that guideline?
A. That --
MS. DAVIDSON: Objection.
THE WITNESS: Yes.
So can we pull it up,

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please?
BY MR. SLATER:
Q. I don't have that. I've never seen it. I don't even know what it is.
A. Okay. So this is EMEA. This is very old, because they are no longer called EMEA.
And what they did was they actually, I think, and I'm not sure, so I'm speculating here, that that was the precursor to M7.
Q. They say that this is -- rephrase.
They say that the valsartan is in accordance with ICH M7.
Do you see that?
A. Yes.
Q. So based on this document, ZHP was applying ICH M7 as of July 14, 2015, correct?
MS. DAVIDSON: Objection.
THE WITNESS: I'm sorry, but it doesn't say that.

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BY MR. SLATER:
Q. They're making a genotoxicity statement and they're representing that the valsartan complies with ICH M7.
That's what the document says, right?
A. It says that the drug substance valsartan manufactured by this is, to the best of our knowledge, in accordance with M7, yes.
Q. They then say, The reagents, intermediates and impurities susceptible of generating genotoxic impurities have been taken into account. No genotoxic impurities are present in the substance.
Do you see that?
A. Yes.
Q. In retrospect, that statement was incorrect, because we know that there were genotoxic impurities in the valsartan, correct?
MS. DAVIDSON: Objection.
THE WITNESS: In 2023 and in

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post June 2018, yes, we know.
Pre June 2018, ZHP didn't know.
MR. SLATER: All right. I'm not going to ask any other questions at this point.
I'm reserving whatever minutes I have left. And depending on how many questions counsel asks, I will intend to continue to ask reasonable follow-up questions.
And I'm reserving all my rights regarding whether or not I need to ask for more time in the future.
So I'm handing it off to defense counsel.
MS. DAVIDSON: Thank you, Adam. I will just have very few questions. I need five minutes first.
VIDEO TECHNICIAN: Would you like to go off the record?

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MS. DAVIDSON: Let's go off the record.
VIDEO TECHNICIAN: We're off the record at 6:25 p.m.
- - -
(Whereupon, a brief recess was taken.)
- - -
VIDEO TECHNICIAN: We're back on the record at 6:34 p.m.
MS. DAVIDSON: Great.
- - -
EXAMINATION
- - -
BY MS. DAVIDSON:
Q. Dr. Afnan, it's late in the evening. I just have a few very quick questions for you.
My first question is, earlier today there was some discussion of the DMF --
A. You froze.
Q. -- is that correct?
A. Sorry. You cut out.

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Can you repeat?
MS. DAVIDSON: I went back upstairs. Okay. It's clearly an upstairs/downstairs thing. Can you guys hear me now?
BY MS. DAVIDSON:
Q. So I said that earlier today I believe there was some discussion of the DMF for the zinc chloride process, and you testified that the DMF is still active; is that correct?
A. The drug master file is still active, yes.
Q. Do you know whether there have been any changes to that drug master file over time?
A. Yes.
Q. And when I say do you know if there have been, maybe that wasn't a great question.
Have there been --
A. Yes.
Q. -- changes in the drug master file over time?

A. Yes, there have been changes to the DMF.
Q. Okay. My other question for you was, earlier today we talked about a WHO document.
MS. DAVIDSON: And can we bring that document back on the screen? Unfortunately, I don't remember what exhibit number it was.
We can either reintroduce it or -- Chris, do you know what document that was? The WHO document, Chris Geddis, master of the documents?
MR. SLATER: He sort of checked out on this thing. He was working on other stuff.
MS. DAVIDSON: He's not here?
MR. SLATER: He's here, but he moved on to some other work.
Exhibit-6.
MS. DAVIDSON: Okay.

BY MS. DAVIDSON:
Q. Dr. Afnan, if you could -- I believe you have Exhibit-6 in your files. I just want to make sure you know which document we're talking about.
A. Yes. It's the -- it's the WHO document 2001.
Q. I just wanted to clarify, do you -- looking at this document, do you know when you first saw it?
A. Actually, I made a mistake, I think, because it looks familiar.
This was presented in -- I saw this after my report. This was present in Dr. Bain's testimony as one of the exhibits of her testimony. So I have not seen it prior to writing my report.
MS. DAVIDSON: Those are my only questions.
THE WITNESS: I apologize.
MR. SLATER: No other questions.
MS. DAVIDSON: Enjoy your dinner, Adam. Have a good night

everybody.
VIDEO TECHNICIAN: If there's nothing further, the time is now 6:37 p.m., this concludes today's testimony from Dr. Ali Afnan. We are now off the record.
- - -
(Whereupon, the deposition concluded at 6:37 p.m.)
- - -

CERTIFICATE

I, Amanda Maslynsky-Miller, Certified Realtime Reporter, do hereby certify that prior to the commencement of the examination, ALI AFNAN, Ph.D., was remotely sworn by me to testify to the truth, the whole truth and nothing but the truth.

I DO FURTHER CERTIFY that the foregoing is a verbatim transcript of the testimony as taken stenographically by me at the time, place and on the date hereinbefore set forth, to the best of my ability.

I DO FURTHER CERTIFY that I am neither a relative nor employee nor attorney nor counsel of any of the parties to this action, and that I am neither a relative nor employee of such attorney or counsel, and that I am not financially interested in the action.

_____
Amanda Miller
Certified Realtime Reporter
Dated: February 10, 2023

(The foregoing certification of this transcript does not apply to any reproduction of the same by any means, unless under the direct control and/or supervision of the certifying reporter.)

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INSTRUCTIONS TO WITNESS

Please read your deposition over carefully and make any necessary corrections. You should state the reason in the appropriate space on the errata sheet for any corrections that are made.

After doing so, please sign the errata sheet and date it.

You are signing same subject to the changes you have noted on the errata sheet, which will be attached to your deposition.

It is imperative that you return the original errata sheet to the deposing attorney within thirty (30) days of receipt of the deposition transcript by you. If you fail to do so, the deposition transcript may be deemed to be accurate and may be used in court.

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ACKNOWLEDGMENT OF DEPONENT

I,_____, do hereby certify that I have read the foregoing pages, 1 - 428, and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.

_____

ALI AFNAN, Ph.D. DATE

Subscribed and sworn to before me this _____ day of _____, 20____.

My commission expires:_____

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Notary Public

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LAWYER'S NOTES

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WORD INDEX